s22

From: Jonathan Chew s47F @infantnutritioncouncil.com>
Sent: Tuesday, 24 September 2024 12:33 PM
To: ANDREWS, Tracey; s47E(c), s47F
Cc: s47E(c), s47F
Subject: Re: Infant Nutrition Council: ACCC draft determination [SEC=OFFICIAL]

Hi Tracey

I'm sorry, I'm on a call from 12pm – 1pm that cannot be moved.

I am free 11am-12pm and 1pm to 3pm tomorrow?

Cheers
Jonathan

From: ANDREWS, Tracey s47E(c), s47F @health.gov.au>
Date: Tuesday, 24 September 2024 at 12:27 PM
To: Jonathan Chew s47F @infantnutritioncouncil.com>, s47E(c), s47F @Health.gov.au>
Cc: s47E(c), s47F @health.gov.au>
Subject: RE: Infant Nutrition Council: ACCC draft determination [SEC=OFFICIAL]

Hi Jonathan

Are you free tomorrow at 12pm for 15 minutes for a quick chat ?

Regards
Tracey

From: Jonathan Chew s47F @infantnutritioncouncil.com>
Sent: Monday, September 23, 2024 6:23 PM
To: ANDREWS, Tracey s47E(c), s47F @health.gov.au>; s47E(c), s47F @Health.gov.au>
Subject: Infant Nutrition Council: ACCC draft determination

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear Tracey,

I spoke earlier today with your colleague s47E(c) s47F about the release of the ACCC draft determination into the reauthorisation of the MAIF Agreement. Subsequently I spoke with s47F in the Minister's office, who asked I get in touch with you. Perhaps we can schedule a call at your convenience about next steps?

Cheers
Jonathan

Jonathan Chew
Chief Executive Officer

Infant Nutrition Council

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M s47F
E s47F @infantnutritioncouncil.com infantnutritioncouncil.com

s22

From: maif <maif@health.gov.au>
Sent: Wednesday, 6 November 2024 12:21 PM
To: WILTON, Kellie; Jonathan Chew; Jane Scott
Cc: maif
Subject: MAIF Complaints Committee Meeting 17 - Agenda Papers [SEC=OFFICIAL]
Attachments: Agenda - MAIF Complaints Committee Meeting 17.pdf; Agenda Papers - MAIF Complaints Committee Meeting 17 including Attachment A-F.pdf

Dear Members

Please see the following documents for the MAIF Complaints Committee Meeting 17, 2:30-430pm on Wednesday 13 November 2024. These documents can be found via the MAIF SharePoint page (see links below) and are also attached for your reference. Please let me know prior to the meeting if you would prefer hard copies of these documents for the meeting day and I am happy to prepare this.

- Agenda: Agenda - MAIF Complaints Committee Meeting 17.pdf
- Agenda papers including Atachment A-F: Agenda Papers - MAIF Complaints Committee Meeting 17 including Attachment A-F.pdf

We look forward to seeing you all next Wednesday in Canberra's Woden Offices, the Yaradhang Building (pronounced Yeh-rah-done, previously Sirius).

Upon arrival, please call myself on (02) s47E(c), s47F and ensure you bring photo ID to assist with the sign in process.

Kind regards,

s47E(c), s47F

MAIF Complaints Committee Secretariat Team
Nutrition Policy Section

Primary and Community Care Group | Population Health Division
Preventive Health and Food Branch
Australian Government Department of Health and Aged Care
E: MAIF@health.gov.au
MDP 570, GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

Marketing in Australia of Infant Formulas (MAIF) Agreement
Complaints Committee Meeting 17
13 November 2024
2.30pm – 4.30pm (AEDT)
Secretariat phone: (02) 6289 7358
Secretariat email: maif@health.gov.au

Agenda

Timing	Agenda Item		Supporting Documents
2.30 (5mins)	1	Welcome and acknowledgement of country	Nil
2.35 (5mins)	2	Update of Declaration of Interest Register and agreement to publish	
2.40 (5mins)	3	Meeting 16 (20 October 2023) a. Action Items	
2.45 (5mins)	4	Complaints from previous meeting – for noting	
2.50 (25mins)	5	New Complaints a. New in scope/ Not yet determined b. New complaints – Determined out of session – for noting	Attachment A
3.15 (30mins)	6	MAIF Guidance Documents a. Clause 7 Guidance b. Electronic Media Guidance	Attachment B, C, D, E, F
BREAK – 3.45 (10mins)			
3.55 (5mins)	7	Department Updates	
4.00 (25mins)	8	Committee matters a. Publishing of complaints on MAIF website b. Committee Membership Update c. Annual reports	
4.25 (5mins)	9	Other Business a. Next Meeting Date – Feb 2025	
4.30	10	Meeting Close	

Marketing in Australia of Infant Formulas (MAIF) Agreement
Complaints Committee Meeting 17

13 November 2024

2.30pm – 4.30pm (AEDT)

Secretariat phone: (02) 6289 7358
Secretariat email: maif@health.gov.au

Agenda

Timing		Agenda Item	Supporting Documents
2.30 (5mins)	1	Welcome and acknowledgement of country	Nil
2.35 (5mins)	2	Update of Declaration of Interest Register and agreement to publish	
2.40 (5mins)	3	Meeting 16 (20 October 2023) a. Action Items	
2.45 (5mins)	4	Complaints from previous meeting – for noting	
2.50 (25mins)	5	New Complaints a. New in scope/ Not yet determined b. New complaints – Determined out of session – for noting	Attachment A
3.15 (30mins)	6	MAIF Guidance Documents a. Clause 7 Guidance b. Electronic Media Guidance	Attachment B, C, D, E, F
BREAK – 3.45 (10mins)			
3.55 (5mins)	7	Department Updates	
4.00 (25mins)	8	Committee matters a. Publishing of complaints on MAIF website b. Committee Membership Update c. Annual reports	
4.25 (5mins)	9	Other Business a. Next Meeting Date – Feb 2025	
4.30	10	Meeting Close	

Item 2 | Update of Declarations of Interest register and agreement to publish (2.35pm)
Member to advise of any updates on conflicts of interest.

The current declarations of interest:

Member	Background and experience	Declarations of interest
Kellie Wilton – Independent representative (Chair)	Midwifery Advisor to the Department of Health and Aged Care Chief Nursing and Midwifery Officer	Former employment at the Australian College of Midwives managing the Baby Friendly Health Initiative (BFHI) program. Declared August 2024
Jane Scott – Public health representative	Former Deputy Head of the School of Public Health at Curtin University.	Recipient of an Australian Government Department of Health, Child and Youth health grant to trial 'Milk Man', a breastfeeding app for fathers from rural and remote Western Australia. Co-investigator on a National Health and Medical Research Council (NHMRC) Project Grant led by the University of Queensland. Chair of the recently formed Australian Breastfeeding Association WHO Code Taskforce. Declared October 2021
Jonathan Chew – Industry representative	Infant Nutrition Council (INC) Chief Executive Officer (CEO)	INC CEO Declared August 2024

Item 3a | Meeting 16 (20 October 2023) – Action Items (2.40pm)

Item	MAIF Complaints Meeting (Date)/ Agenda Item	Action	Who	When	Status
1	**Meeting 15: 19 April 2023** Item 5 Complaints previous meeting	Secretariat to consider the guidance updates for cross national promotion.	Secretariat	20 Nov 2023	**Closed** - to be considered in the review of MAIF guidance document: Electronic Media (Agenda Item 6b).
2	**Meeting 15: 19April 2023** Item 6 New complaints	Secretariat to note the Therapeutic Goods Administration's social media advertising guide when considering testimonial social media advice.	Secretariat	20 Nov 2023	**Closed** - to be considered in the review of MAIF guidance document: Electronic Media (Agenda Item 6b).
3	**Meeting 16: 20 October 2023** Item 3b Meeting 15 (19 April 2023) Action Items	Committee to provide any comments on the summary of the signatories forum. Once comments are provided, Secretariat to send the summary of the signatories forum to the Signatories.	Committee/Secretariat	3 Nov 2023	**Complete** - Secretariat finalised the signatories forum summary and distributed with a committee update.
4	**Meeting 16: 20 October 2023** Item 4 Complaints from previous meeting – for final determination	Secretariat to update guidance to include a limitation on timeframes. Suggested wording to be considered, as provided by the Chair.	Secretariat	20 Nov 2023	**Closed** - to be considered in the review of MAIF guidance document: Electronic Media (Agenda Item 6b).
5	**Meeting 16: 20 October 2023** Item 5 New complaints	Secretariat to provide guidance to signatories regarding change in stock or availability communications.	Secretariat	20 Nov 2023	**Closed** - to be considered in the review of MAIF guidance document: Electronic Media (Agenda Item 6b).
6	**Meeting 16: 20 October 2023** Item 6 MAIF guidance documents – Clause 7 guidance document	Committee to provide final comments within a week of Meeting 16 (20 Oct) on Clause 7 guidance documents.	Members	27 Oct 2023	**In Progress** - Committee endorsed the documents with one final review of wording relating to competitions needed. Updated wording for members consideration at Agenda Item 6a.

Item 4 | Complaints from previous meeting (2.45pm)

Members to note the following complaints have been finalised since the previous meeting (Meeting 16, 20 October 2023).

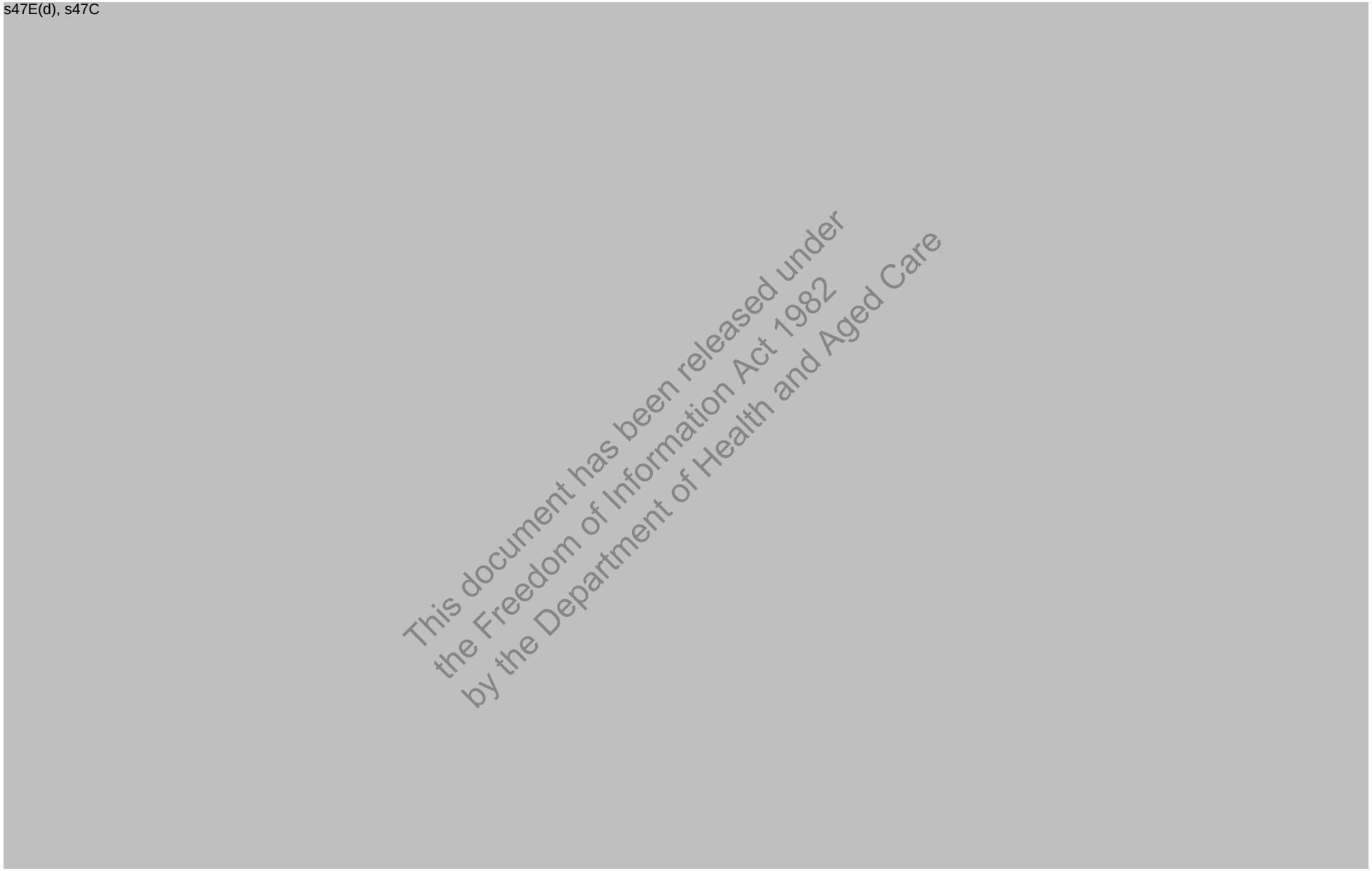
Complaint Reference	Company	Final Determination	Final determination letters	
			Complainant	Company
2223-35	s 47G	No Breach	Complete	Complete
2223-52	The LittleOak Company	Breach	Complete	Complete
2223-54	The LittleOak Company	Breach	Complete	Complete
2223-55	Sprout Organic	Breach	Complete	Complete
2223-57	The LittleOak Company	Breach	Complete	Complete
2223-65	s 47G	Out of Scope	Complete	N/A
2223-78		Out of Scope	Complete	N/A
2223-79		Out of Scope	Complete	N/A
2223-83	The LittleOak Company	Breach	Complete	Complete
2223-84	Sprout Organic	Breach	Complete	Complete
2223-87, 89, 90, 91, 92	Sprout Organic	Breach	Complete	Complete
2223-93	s 47G	Out of Scope	Complete	N/A
2223-94		Out of Scope	Complete	N/A
2223-95		No Breach – scope un-determined	Complete	Complete
2223-96	Sprout Organic	Breach	Complete	Complete
2223-97	Australian Dairy Nutritionals	Breach	Complete	Complete
2223-98	Australian Dairy Nutritionals	Breach	Complete	Complete
2223-99	Australian Dairy Nutritionals	Breach	Complete	Complete
2223-100	Sprout Organic	Breach	Complete	Complete

Item 5a | New complaints – New in-scope or not yet determined (2.50pm)

Members to deliberate on complaints and make final determinations. Refer to **Attachment A** for the collated complaint forms and company responses.

s47E(d), s47C

s47E(d), s47C



s47E(d), s47C


This document has been released under
the Freedom of Information Act 1982
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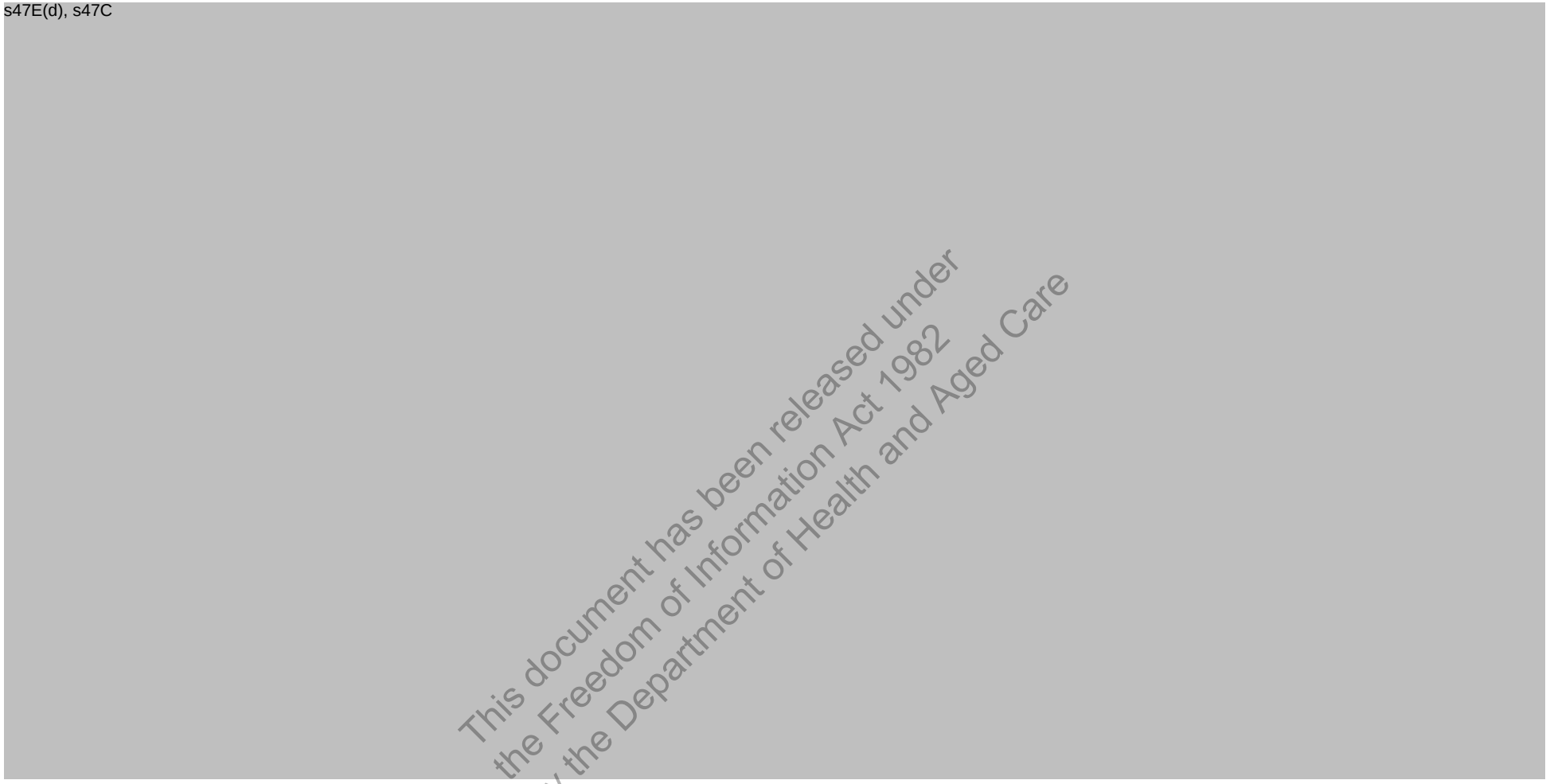
s47E(d), s47C



Item 5b | New complaints – Determined out of session – for noting

Of the 19 new complaints reviewed out of session by members

- Members agreed on the final determination for 12 of the complaints.
- 1 complaint deemed a breach and 11 deemed out of scope by members.

Complaint Reference	Company	Final Determination/Reason	Final determination letters	
			Complainant	Company
2324-01	s 47G	Out of scope – Toddler milk	In progress	In progress
2324-06	The LittleOak Company	Breach	In progress	In progress
2324-08	s 47G	Out of scope – Retailer	Complete	N/A
2324-09		Out of scope – Toddler milk	Complete	N/A
2324-10		Out of scope – Non signatory	Complete	N/A
2324-11		Out of scope – Non signatory	Complete	N/A
2324-12		Out of scope – Non signatory	Complete	N/A
2425-01		Out of scope – Non signatory	Complete	N/A
2425-03		Out of scope – Retailer	Complete	N/A
2425-04		Out of scope – Retailer	Complete	N/A
2425-05		Out of scope – Retailer/toddler milk	Complete	N/A
2425-06		Out of scope – Non signatory	Complete	N/A

Item 6 | MAIF guidance documents (3.15pm)
Item 6a | Clause 7 Guidance:
That Members:

- **Note** the background regarding Clause 7 Guidance Document (Clause 7 Document).
- **Discuss** the Clause 7 Guidance Document at **Attachment B** and whether additional amendments should be made to align advice on 'Competitions'.

Background:

- Guidance on Clause 7 limits the type of information that signatories can provide to health care professionals on infant formula products.
- At the last meeting (20 October 2023), Members endorsed updates to the Clause 7 Guidance but requested that Secretariat consider the wording around 'competitions' which allows for prizes of a low value not exceeding $100 (point under sub-heading 'Inducements').
- Guidance by Medicines Australia (see **Attachment C**, Section 2.7 Competitions), notes that competitions may be run by member companies, but no prizes may be offered.
- The following change to the Clause 7 Guidance Document would achieve alignment with the Medicines Australia approach:
    - Competitions, included in information material for health professionals, which are clearly for the purpose of emphasising scientific and factual information only, may be acceptable. Such competitions should not be an inducement to promote infant formulas. No prize or gift may be offered under any circumstances.

Item 6b | Electronic Media Guidance:
That Members:

- **Note** the background regarding the Electronic Media Guidance Document (Electronic Media Guidance).
- **Discuss** the Electronic Media Guidance at **Attachment D** and workshop initial reactions and agree next steps, including providing direction to the Department on preferred activities to support this work and timeframes for implementation.

Background:

- The Electronic Media Guidance provides guidance on the application of the MAIF Agreement to activities undertaken on electronic media including social media.
- Work to amend the guidance to clarify the application of the MAIF Agreement in these contexts has been on hold pending the finalisation of the independent review undertaken by Allen + Clarke Consulting.
- As outlined in the Department's submission to the Australian Competition and Consumer Commission (ACCC) Draft Determination, the Department has committed to working with the MAIF Complaints Committee to update the Electronic Media Guidance to clarify that social media promotion, including social media influencing, is subject to the MAIF Agreement.

- In its submission, the Department also acknowledged that since the development of this guidance there has been developments in other areas, which were highlighted in the submission, namely:
    - the WHO has developed guidance on regulatory measures aimed at limiting the digital marketing of breast-milk substitutes (**Attachment E**), and
    - the Therapeutic Goods Administration (TGA) has published the 'Advertising Code' that sets standards for advertising therapeutic goods, including on social media (**Attachment F**).
- Based on previous engagements, Signatories have suggested clearer definitions would be helpful and that the guidance provide greater detail on:
    - the definition of what a paid influencer is;
    - hash tag use, and
    - sharing and re-sharing content
- There is currently no advice on timeframes around social media complaints received. The Committee have previously discussed updating guidance to signatories on complaint timeframes and suggested the below wording:
    - 'Complaints should have an incident date within the past 12 months. Complaints be submitted within 3 months of the incident. Complaints where the incident has occurred over 12 months ago will not be considered. For complaints relating to social media please take a screen shot of the complaint with a timestamp attached.'
- Below are examples of past complaints related to social media that were found to be in breach of the MAIF Agreement:

Issues	**Context**
Use of social media "stories"	Use of social media stories which only appear for a short window of time (e.g. 24 hours) before disappearing from the company's social media page. Advertising and promotion of infant formula, even if it is only available for viewing temporarily is still considered a breach of the MAIF Agreement.
Images which depict infants	Images which depicts infants even without specific mention of infant formula.
Re-posted images and text	Re-posted images and text promoting infant formula on the signatory's social media pages, even if they didn't originate from the signatory's social media accounts, can be considered a breach of the MAIF Agreement. For example, sharing or re-posting a mother's post including a mothers product testimonial, blog post relating to infant formula and breastfeeding.
Videos or images posted on social media, original or re-shared	Videos or images posted on social media, original or re-shared which don't specifically discuss or reference infant formula but have infant formula images in the background of the video/image.

The use of hashtags and wording on posts, images and videos (captions)	Hashtags or captions which promote infant formula products, can be used by members of the public to search for topics and posts of interest. If your post is about toddler milk products, buta hashtag that refers to babies, infant feeding, infant formula etc. is included – this can still constitute a breach of the MAIF Agreement.
Advertising discounts on entire range which includes infant formula	Discounts advertised for entire product range and not specifying which products are part of the discount sale is misleading and inadvertently promotions infant formula products.
Testimonial posts	Testimonial posts which are either re-shared or directly posted to a signatories' social media site if referring to infant formula products, breastfeeding journeys, blog posts that are promotional of infant formula are considered to be a breach of the MAIF Agreement. The TGA social media guidance may have further information on this.
Change in stock	It is acceptable to notify the public that a product is back in stock for a limited time period using non-promotional information only. Advertising a product is 'now available' (example: at a new location) is considered a breach of the MAIF Agreement.
Posting of Infant formula content/information on social media	Examples of this are FAQ's and Q&A responses from signatories' websites that are posted to Instagram stories from but do not have the breastfeeding statement preface. Without the breastfeeding statement this is a breach.
Cross national promotion	Sharing posts from international branches of a signatory's company that include infant formula references (image, wording, product ranges), other examples include a signatory advertising that they are expanding their product range into international markets (Item 1 in the action table)
Sponsored advertising on social media of infant formula	A sponsored post is a social media post that a company has paid to promote. Sponsored advertising of infant formula is promotional and a breach of the MAIF Agreement.
Promoting a product award	Specifically for infant formula awards - posts notifying the public of a company's award-winning product, similarly that an award has been won for an infant formula product. This type of post is not for educational purposes and is considered promotional and a breach of the MAIF Agreement.

Item 7 | Departmental Updates (3:55pm)

Members to note the below Departmental updates:

- The Department has provided a submission to the ACCC draft determination process supporting re-authorisation of the MAIF Agreement for two years.
- As outlined in the Departments submission, the Australian Government is committed to mandating the MAIF Agreement, proposing a two-year timeframe to put mandatory controls in place.
- In the interim, the Government has committed to practical steps to strengthen the voluntary arrangement during the transition period, in line with recommendations from the MAIF Agreement Review:
    - Strengthen the digital marketing guidance in collaboration with the MAIF Complaints Committee
    - Investigate technology-enabled solutions for monitoring digital marketing
    - Expand the MAIF Complaints Committee to include one additional independent member
    - Uplift the governance arrangements to support greater transparency and timeliness of decision-making including quarterly committee meetings, publishing meeting dates in advance, improving the complaints process, updating committee governance documents available on the Department's website and explore the viability of a live decisions dashboard of incoming complaints. The Department also committed to undertaking quarterly monitoring of compliance with the MAIF Agreement to reduce the burden on members of the public and interested parties.

Item 8 | Committee matters (4:00pm)
Item 8a| Publishing of complaints on the MAIF website
Members to comment on the appropriateness, or otherwise, of publishing final complaint outcomes from Meeting 16 (15 October 2023).

Background:

- On 26 September 2024, the Secretariat finalised and sent the final determination letters following the decisions of the last MAIF Complaints Committee Meeting 16 held on 15 October 2023. s47G replied seeking the Department not to publish its breaches on the website noting issues with the timeliness and transparency of the complaints handling process and time conceded. s47G alleges matters were either rectified or removed well before the complaint was even lodged and publishing would be defamatory.
- The timeline of the complaints s47G refers is outlined below:

Complaint	Complaint and Final Determination	Date of incident	Date complaint was made	Date reviewed by committee	Date final determination was sent
s47G, s47E(d)					

- The Department will consider Members views, internal Health Legal advice and other relevant factors in making a final decision on this matter.

Item 8b| Committee Membership Update

That Members:

- **Note** as part of strengthening the voluntary arrangements and consistent with the MAIF Review, the MAIF Complaints Committee will be expanded.
- **Discuss** the desired skill set required for the additional independent member and recommend suitable candidates for the Department's consideration.

Item 8c| Annual Reports

Members to discuss the proposed updates to the upcoming Annual Report to support streamlining the complaints publishing process.

Background:

- Complaint outcomes are published on the Department's website here and in the Annual Reports here. Currently, the Department's website only displays the current financial year complaints and previous complaint details are found in the Annual Reports. The normal process is for all complaints to be published on the department's website following committee final determination. The complaints are then summarised a second time and published in the Annual Reports (released every financial year).
- The Secretariat is yet to prepare the 2023-24 Annual Report.
- Secretariat propose changing the structure of the upcoming 2023-24 Annual Report (and beyond) to remove the table summary of each complaint. Instead detailed per complaint outcomes would be retained on the Department's website. This approach would streamline the annual reporting process, reduce duplication and free up Secretariat resources for higher impact work.

Item 9 | Other Business (4.25pm)

Item 9a| Next meeting date

Members to discuss and agree on meeting dates for 2025 to be held virtually.

Suggested to be on the third Wednesday of every month unless members are unavailable.

- 19 February 2025
- 21 May 2025
- 20 August 2025
- 19 November 2025

Item 10 | Meeting Close (4:30pm)

Attachments:

Use links below to jump to the attachments

Attachment A – New Complaints for further discussion

Attachment B – Clause 7 Guidance Document

Attachment C – Excerpt of Medicines Australia Code of Conduct Guidelines – Section 2.7 Competitions.

Attachment D – MAIF Electronic Media Guidance Document.

Attachment E – WHO Guidance on regulatory measures aimed at restricting digital marketing of breast-milk substitutes Attachment F – TGA electronic media guidance

Attachment A

New complaints for discussion

Use links below to jump to a complaint

2324-02 – s47G	
Complaint	Company Response
2324-07 – s47G	
Complaint	Company Response
2324-03 – s47G	
Complaint	Company Response
2324-04 – s47G	
Complaint	Company Response
2324-05 – s47G	
Complaint	Company Response
2425-02 – s47G	
Complaint	
2425-07 – s47G	
Complaint	Company Response

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frontiers | Frontiers in Nutrition

ORIGINAL RESEARCH
published: 06 July 2022
doi: 10.3389/fnut.2022.920362

Infant Formula With a Specific Blend of Five Human Milk Oligosaccharides Drives the Gut Microbiota Development and Improves Gut Maturation Markers: A Randomized Controlled Trial

Miroslava Bosheva[1], Istvan Tokodi[2], Aleksander Krasnow[3], Helle Krogh Pedersen[4], Oksana Lukjancenko[4], Aron C. Eklund[4], Dominik Grathwohl[5], Norbert Sprenger[6], Bernard Berger[6], Colin I. Cercamondi[7] and 5 HMO Study Investigator Consortium†*

[1] University Multiprofile Hospital for Active Treatment "St. George" Medical University, Plovdiv, Bulgaria, [2] Infant and Children's Department, St. George's Hospital, Székesfehérvár, Hungary, [3] Gdansk Health Center, Gdańsk, Poland, [4] Clinical Microbiomics, Copenhagen, Denmark, [5] Biostatistics and Data, Nestlé Research, Lausanne, Switzerland, [6] Nestlé Institute of Health Sciences, Nestlé Research, Lausanne, Switzerland, [7] Nestlé Product Technology Center – Nutrition, Société des Produits Nestlé S.A., Vevey, Switzerland

Background: Human milk oligosaccharides (HMOs) have important biological functions for a healthy development in early life.

Objective: This study aimed to investigate gut maturation effects of an infant formula containing five HMOs (2′-fucosyllactose, 2′,3-di-fucosyllactose, lacto-N-tetraose, 3′-sialyllactose, and 6′-sialyllactose).

Methods: In a multicenter study, healthy infants (7–21 days old) were randomly assigned to a standard cow's milk-based infant formula (control group, CG); the same formula with 1.5 g/L HMOs (test group 1, TG1); or with 2.5 g/L HMOs (test group 2, TG2). A human milk-fed group (HMG) was enrolled as a reference. Fecal samples collected at baseline (n∼150/formula group; HMG $n = 60$), age 3 (n∼140/formula group; HMG $n = 65$) and 6 (n∼115/formula group; HMG $n = 60$) months were analyzed for microbiome (shotgun metagenomics), metabolism, and biomarkers.

Results: At both post-baseline visits, weighted UniFrac analysis indicated different microbiota compositions in the two test groups (TGs) compared to CG ($P < 0.01$) with coordinates closer to that of HMG. The relative abundance of *Bifidobacterium longum* subsp. *infantis* (*B. infantis*) was higher in TGs vs. CG ($P < 0.05$; except at 6 months: TG2 vs. CG $P = 0.083$). *Bifidobacterium* abundance was higher by ∼45% in TGs vs. CG at 6-month approaching HMG. At both post-baseline visits, toxigenic *Clostridioides difficile* abundance was 75–85% lower in TGs vs. CG ($P < 0.05$) and comparable with HMG. Fecal pH was significantly lower in TGs vs. CG, and the overall organic acid profile was different in TGs vs. CG, approaching HMG. At 3 months, TGs (vs. CG) had

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†Members of the 5 HMO Study Investigator Consortium are provided at the end of the manuscript

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higher secretory immunoglobulin A (sIgA) and lower alpha-1-antitrypsin ($P < 0.05$). At 6 months, sIgA in TG2 vs. CG remained higher ($P < 0.05$), and calprotectin was lower in TG1 ($P < 0.05$) vs. CG.

Conclusion: Infant formula with a specific blend of five HMOs supports the development of the intestinal immune system and gut barrier function and shifts the gut microbiome closer to that of breastfed infants with higher bifidobacteria, particularly *B. infantis*, and lower toxigenic *Clostridioides difficile*.

Clinical Trial Registration: [https://clinicaltrials.gov/ct2/show/], identifier [NCT03722550].

Keywords: human milk oligosaccharides (HMOs), infant formula, gut microbiota, bifidobacteria, *Bifidobacterium longum* subsp. *infantis* (*B. infantis*), *Clostridioides (C.) difficile*, intestinal immune response, gut maturation

INTRODUCTION

In human milk, the third largest solid component after lactose and lipids is a group of over 160 structurally diverse oligosaccharides known as human milk oligosaccharides (HMOs) (1, 2). Three main categories of HMOs are generally described including neutral fucosylated [e.g., 2′fucosyllactose (2′FL) and 2′,3-di-O-fucosyllactose (DFL)], neutral non-fucosylated [e.g., lacto-N-tetraose (LNT)], and acidic sialylated [e.g., 3′sialyllactose (3′SL) and 6′sialyllactose (6′SL)] oligosaccharides (3–6). HMOs play diverse and important roles in the development of infants starting with their prebiotic function, which supports the establishment and maintenance of a balanced gut microbiota (2, 6–8). HMOs have been long recognized to drive the *Bifidobacterium* dominance in breastfed infants. Not all members of the *Bifidobacterium* genus can metabolize HMOs. *Bifidobacterium longum* subsp. *infantis* (*B. infantis*) is known as a dedicated HMO consumer and able to proliferate in the presence of HMOs (7). Additionally, a role of HMOs in immune protection has been demonstrated *via* anti-adhesive antimicrobial effects (8–10), regulation of intestinal epithelial cell response (6, 7), and modulation of immune responses *via* direct effects on immune cells and cytokine secretion (11–13). Furthermore, potential benefits of HMOs on brain development have been reported (14, 15).

Breastfeeding is the reference for infant nutrition, and the lack of HMOs in infant formula is likely one of the factors contributing to differences in health outcomes that have been observed between breastfed and formula-fed infants (16). Advances in technology now allow the synthesis of HMOs, and some of them are being added to formulas to provide infants who cannot be fed with human milk with identical oligosaccharides to those found in human milk (7). Clinical trials have demonstrated safety and good tolerance of infant formulas supplemented with 2′FL alone (17, 18), the combination of 2′FL and lacto-N-neotetraose (LNnT) (19, 20), and a blend of five HMOs (21). HMOs have been shown to play an important role in the development of the intestinal microbiome in breastfed infants (22, 23), and more recently, infant formula with 2′FL and LNnT was shown to promote a microbiome more similar to the human milk-fed reference than formula not containing HMOs (24). In another trial, infants fed a formula containing 2′FL and galacto-oligosaccharides had plasma and *ex vivo* inflammatory cytokine profiles more similar to the breastfed reference than control infants fed a formula with galacto-oligosaccharides alone (25).

With more HMOs becoming available, it is possible to supplement formulas with blends of HMOs providing structurally diverse and complex oligosaccharides to formula-fed infants. Our study evaluated for the first time the gut maturation effects (microbiota, metabolites, and selected maturation markers) of an infant formula containing a specific blend of five HMOs (2′FL, DFL, LNT, 3′SL, and 6′SL) that is based on the HMO profile found in human milk and covers the major HMOs from all three categories. We hypothesized that infants receiving a starter formula with the five-HMO blend for 6 months would have a gut microbiota composition and metabolic activity more similar to that observed in human milk-fed infants and improved gut maturation markers than their control peers. This article reports the secondary outcomes up to 6 months of age of a 15-month study.

Abbreviations: AAT, alpha-1-antitrypsin; 2′FL, 2′fucosyllactose; 3′SL, 3′sialyllactose; 6′SL, 6′sialyllactose; *B.*, *Bifidobacterium*; *C. difficile*, *Clostridioides difficile*; CG, control group; DFL, 2′,3-di-O-fucosyllactose; HMG, human milk group; HMOs, human milk oligosaccharides; IF, infant formula; LNT, lacto-N-tetraose; LNnT, lacto-N-neotetraose; MGS, metagenomic species; PCoA, principal coordinates analysis; PD, phylogenetic diversity; PERMANOVA, permutational multivariate analysis of variance; SCFA, short-chain fatty acid; sIgA, secretory immunoglobulin A; TG1, test group 1; TG2, test group 2.

SUBJECT AND METHODS

Study Design

This randomized, controlled, double-blind trial conducted between September 2018 and November 2021 at 32 study sites in Bulgaria, Hungary, and Poland consisted of three randomized formula-fed groups and a non-randomized human milk-fed group (HMG) as reference. The study was conducted according to the Declaration of Helsinki and the International Conference on Harmonization Guidelines for good clinical practice. All procedures involving human subjects were approved by the Scientific and Research Ethics Committee of Medical Research Council (Budapest, Hungary), the Bioethics Committee at the

Regional Medical Chamber (Gdańsk, Poland), and the Ethics Committee of the Scientific Research at Medical University (Sofia, Bulgaria). Written informed consent was obtained prior enrollment from the parents of all infants. The trial was registered on ClinicalTrials.gov as NCT03722550.

The overall study included a follow-up up to 15 months of age with formula-fed infants consuming a starter infant formula (IF) from enrollment to 6 months, transitioning to a follow-up formula from 6 to 12 months, and followed by growing-up milk from 12 to 15 months. This report encompasses the first 6 months of the study during which participants were expected to consume the assigned IF (or breastmilk in HMG) continuously until 6 months of age, with the addition of complementary foods permitted after 4 months of age. Subject demographic data were collected at the enrollment visit. Fecal samples were collected at enrollment (baseline), 3, and 6 months of age in a random subset of infants whose parents agreed for the stool sampling ("first-in, first-served principle"). Parents were instructed to immediately freeze the collected fecal samples in their freezer at home (∼−20°C) and to bring them within 3 days to the study site where samples were frozen at −80°C until analysis. Transport to the study sites was done in cooling bags containing sufficient cool packs to keep samples frozen.

Study Participants

All infants were required to be healthy and full-term, with birth weight between 2,500 and 4,500 g, and aged ≥ 7– ≤21 days at enrollment. For formula-fed infants, parents had elected to formula feeding prior to enrollment. For the HMG, infants had to consume human milk exclusively from birth to enrollment, and their parents had elected to continue exclusive breastfeeding at least until 4 months of age. Infants with conditions requiring feedings other than those specified during the trial period or requiring complementary foods at or prior to enrollment were not eligible, as were infants with evidence of major congenital malformations, documented or suspected congenital infections, a history of admission to the neonatal intensive care unit for any reason except jaundice phototherapy, and participating in other clinical trials. In addition, infants having used any medication known or suspected to affect fat digestion, absorption or metabolism, stool characteristics, growth, or gastric acid secretion were not eligible.

Interventions

The three formula-fed groups were the control group (CG) fed a standard IF without HMOs, test group 1 (TG1) fed the same standard IF with a concentration of 1.5 g/L of the five-HMO blend, and test group 2 (TG2) fed the same standard IF with a concentration of 2.5 g/L of the five-HMO blend. The concentrations of the five HMOs in TG1 and TG2 were 0.87 and 1.45 g/L for 2′FL, 0.10 and 0.14 g/L for DFL, 0.29 and 0.48 g/L for LNT, 0.11 and 0.18 g/L for 3′SL, and 0.14 and 0.24 g/L for 6′SL, respectively. These concentrations are all in the range of that reported in human milk for the individual HMOs (26–30). The standard IF was a bovine milk-based whey predominant term infant formula with 67 kcal/100 mL reconstituted formula, consisting of 1.9 g intact protein (70% whey/30% casein)/100 kcal, 11.1 g carbohydrates/100 kcal, and 5.3 g lipids/100 kcal.

Formula-fed infants were randomized to CG, TG1, or TG2 using Medidata Balance, and randomization was stratified by study center, sex, and mode of delivery with an equal study infant allocation ratio of 1:1:1 for CG:TG1:TG2. The study was double blinded with the identity of the specific product masked to all parents of enrolled infants, study investigators, and study staff using individual coding.

Microbiome Analysis and Ecological Measures

Microbial DNA was extracted from frozen feces, purified, and shotgun sequenced with 2 × 150 bp sequencing, as described previously (15). Taxonomic relative abundances were calculated using the metagenomic species (MGS) approach, which enables the quantification of both known characterized and uncharacterized microbial species (31) (see also **Supplementary Methods**).

A phylogenetic tree connecting the MGSs was generated using previously identified conserved genes (**Supplementary Methods**). Alpha diversity as Faith's phylogenetic diversity (PD) (32) and beta diversity as weighted UniFrac distance (33) were calculated using this tree with the *PhyloMeasures* and *phyloseq* R packages, respectively. Additional alpha diversity indexes, including richness and Shannon diversity, were calculated independently for gene, MGS, and genus. Centroids for vaginally delivered HMG infants were calculated at each timepoint using all principal coordinates analysis (PCoA) coordinates, and distance from a sample of the respective timepoint to the HMG centroid ($d_{vaginal\ delivered\ HMG-centroid}$) was calculated as the Euclidean distance in this PCoA space. All distances and alpha diversity measures were calculated using rarefied abundances.

Analysis of Fecal Biomarkers, pH, and Organic Acids

Commercially available ELISA kits were used to analyze fecal biomarkers at baseline, age 3, and 6 months, including secretory immunoglobulin A (sIgA), calprotectin (both Immundiagnostik AG, Bensheim, Germany), and alpha-1-antitrypsin (AAT; BioVendor – Laboratorni medicina a.s., Brno, Czech Republic).

Fecal pH and organic acids (including lactate, acetate, butyrate, isobutyrate, propionate, valerate, and isovalerate) were assessed at baseline, 3, and 6 months of age using pH indicator paper (pH range 1–10; Merck, Darmstadt, Germany) and validated liquid chromatography-tandem mass spectrometry according to a modified previously published method (34), respectively.

Statistics

For weighted UniFrac analysis, permutational multivariate analysis of variance (PERMANOVA) tests assessing marginal effects of the terms were performed using the adonis2 function from the *vegan* R package with 1,000 permutations (35). Alpha

diversity indexes and taxonomical abundances were compared among the groups using the Kruskal–Wallis H test with *post hoc* Dunn's test. Fisher's exact test was used to assess differences in taxonomical prevalence. To compare $d_{vaginal\ delivered\ HMG-centroid}$ between the feeding groups, we used the Mann–Whitney U test. For the Kruskal–Wallis H test and the corresponding pairwise tests, all considered taxa detected in at least 10 formula-fed infants in the given comparison were subjected to the testing scheme. For Fisher's exact test and the corresponding pairwise tests, we included all entities which were i) detected in $\geq$ 3 samples and ii) undetected in $\geq$ 3 samples from formula-fed infants in the given comparison. All statistical tests were run using R software (v. 4.0.3). The dataset for microbiota analyses consisted of infants who provided a stool sample at any timepoint and were compliant with the study feeding on $\geq$ 80% of the days. Up to 4 months of age, a compliant day was defined as a day on which the study product (or human milk in the reference group) was exclusively fed (i.e., no complementary foods or other formulas). From 4 to 6 months of age, a compliant day was defined as a day on which at least one serving of the study product was consumed. For the HMG, there were no specific requirements for the period between 4 and 6 months age. For bifidobacteria analysis, four of nine *Bifidobacterium* (sub)species were defined as infant-type *Bifidobacterium* (sub)species based on a previous publication, including *B. longum* subsp. *infantis*, *B. longum* subsp. *longum*, *B. bifidum*, and *B. breve* (36), and the sum of their relative abundance was compared between the groups.

Fecal pH, organic acids, and biomarkers were based on grams of fecal dry weight and were log-transformed for analysis if needed. Intervention differences at 3 and 6 months of age were examined in ANCOVA models adjusted for baseline values of the measure of interest or Wilcoxon test for infants providing a baseline sample and a sample at the respective timepoint. Short-chain fatty acids (SCFA; acetate, butyrate, isobutyrate, propionate, valerate, isovalerate) were analyzed as a proportion of total SCFA. Analyses were conducted using SAS/STAT software version 9.4 of the SAS System (SAS Institute Inc., Cary, NC, United States).

This article reports the secondary endpoints of a study for which the sample size calculation was based on the two co-primary endpoints: growth at 4 months and incidence of respiratory tract infections at 15 months (ClinicalTrials.gov: NCT03722550); therefore, no sample size calculation is available for the endpoints reported herein.

RESULTS

Participants

Of the 693 randomized formula-fed infants (CG, n = 233; TG1, n = 230; TG2, n = 230) and 96 non-randomized human milk-fed infants in the HMG who were enrolled for the overall study, the stool samples of 535 infants were analyzed and included in this report (CG, n = 155; TG1, n = 158; TG2, n = 153; HMG, n = 69; **Figure 1**). Baseline characteristics of the infants included in this report are shown in **Table 1** and were largely comparable among the feeding groups, except for longer maternal and paternal education and slightly older gestational age at birth in HMG compared with the formula-fed groups.

Gut Microbiome

At baseline, no significant differences in alpha diversity indexes were observed among the formula-fed groups (all pairwise $P > 0.05$; **Figure 2A** and **Supplementary Figures 1, 2**). At 3 months of age, gene and genus Shannon index were lower in TG1 than in CG ($P < 0.05$) (**Supplementary Figure 2**). At 6 months of age, Faith's PD, richness and Shannon index at gene, MGS, and genus level were lower in TG1 than in CG (all $P < 0.05$), approaching HMG (**Figure 2A** and **Supplementary Figures 1, 2**). In TG2, richness and Shannon index at the genus level were lower than those in CG at 6 months of age ($P < 0.05$), approaching HMG. All alpha diversity indexes in HMG were significantly lower than those in each of the three formula-fed groups at each timepoint (**Figure 2A** and **Supplementary Figures 1, 2**).

Beta diversity analysis, based on weighted UniFrac and PERMANOVA and visualized with PCoA, revealed a difference in gut microbiota composition among the four groups at all three timepoints (PERMANOVA, $P \leq 0.005$, **Figure 2B** and **Supplementary Table 1**). In an analysis of the three formula-fed groups without HMG, no significant difference was observed at baseline (PERMANOVA, $P = 0.838$). However, significant differences were observed among the formula-fed groups at 3 and 6 months of age (R^2 = 1.6%, $P < 0.001$ and R^2 = 3.0%, $P < 0.001$, respectively). Between group comparisons showed that test groups and HMG were significantly different from CG at both post-baseline timepoints. Each test group was significantly different from HMG at baseline and 3 months, but TG1 not at 6 months (TG2 remained significantly different at 6 months, albeit the level of significance decreased with time from $P < 0.001$ to $P = 0.04$), indicating that the test groups transitioned toward HMG (**Figure 2B** and **Supplementary Table 1**).

To assess microbiota similarities of formula-fed infants with vaginally delivered human milk-fed infants, we calculated the phylogenetic distance between each sample and the centroid of the vaginally delivered HMG at the same timepoint ($d_{vaginal\ delivered\ HMG-centroid}$; **Figures 3A–C**). At baseline, we did not detect differences in $d_{vaginal\ delivered\ HMG-centroid}$ between the formula-fed groups (all pairwise $P > 0.05$). At 3 months, both TG1 ($P = 0.001$) and TG2 ($P = 0.022$) were closer to the vaginally delivered HMG centroid than CG, which was further strengthened at 6 months (both TG1 and TG2; $P < 0.0001$), indicating that the test groups shifted their microbiota composition toward vaginally delivered HMG. We next performed the same analysis on the subsets of cesarean- and vaginally delivered infants (**Figures 3D–I**). At baseline, $d_{vaginal\ delivered\ HMG-centroid}$ was similar for the formula-fed groups in both subsets. At 3 months, we detected no differences between the vaginally delivered formula-fed groups and a lower $d_{vaginal\ delivered\ HMG-centroid}$ in cesarean-delivered TG1 compared to cesarean-delivered CG ($P = 0.004$). At 6 months, in both delivery subsets, $d_{vaginal\ delivered\ HMG-centroid}$ was significantly lower in both TG1 and TG2 than in CG (both $P < 0.05$;

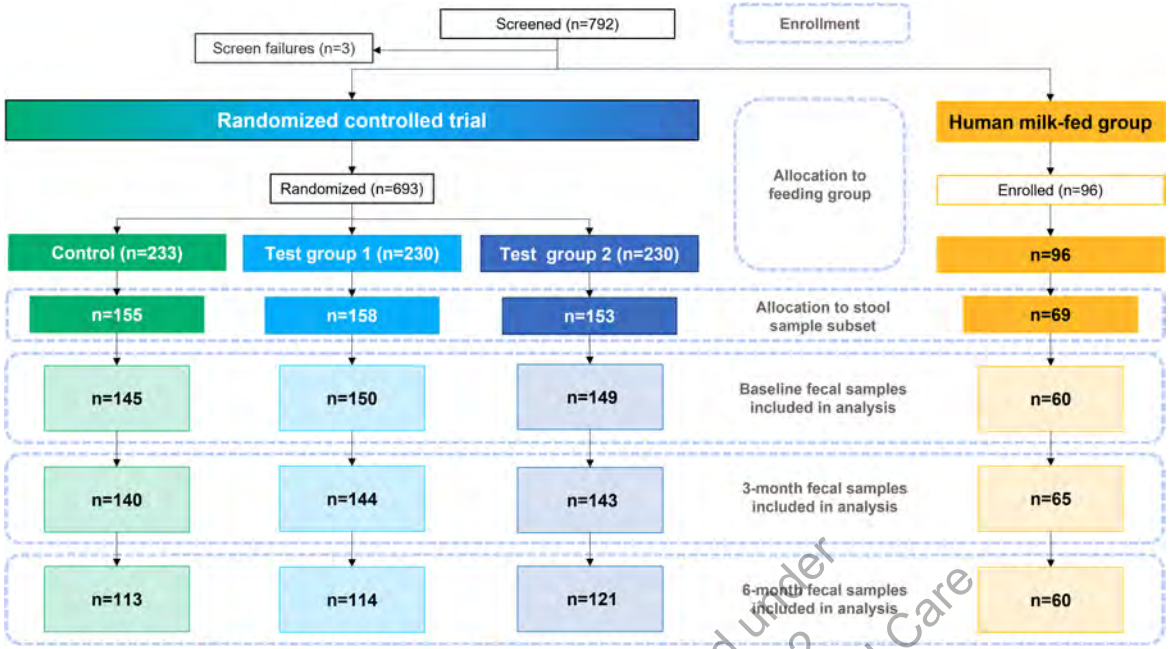

FIGURE 1 | Study participant flowchart. Control was without HMOs; test group 1 was with 1.5 g HMOs/L; test group 2 with 2.5 g HMOs/L. HMOs human milk oligosaccharides.

TABLE 1 | Demographic characteristics, by feeding group (n = 535).

	CG (n = 155)	TG1 (n = 158)	TG2 (n = 153)	HMG (n = 69)	*P-value*[a]
Age at baseline (days)	14.5 ± 4.6	14.7 ± 4.5	14.3 ± 4.5	15.4 ± 3.8	0.316
Sex					0.426
Male	80 (51.6%)	78 (49.4%)	77 (50.3%)	42 (60.9%)	
Female	75 (48.4%)	80 (50.6%)	76 (49.7%)	27 (39.1%)	
Gestational age at birth (weeks)	38.7 ± 1.3	38.7 ± 1.2	38.7 ± 1.1	39.1 ± 1.0	0.047
Delivery mode					0.501
Vaginal	64 (41.3%)	64 (40.5%)	63 (41.2%)	35 (50.7%)	
Cesarean	91 (58.7%)	94 (59.5%)	90 (58.8%)	34 (49.3%)	
Complementary foods by age 6 months (yes)	138 (94.5%)	144 (96.6%)[b]	144 (96.0%)	58 (87.9%)	0.079
Maternal education (years)	13.7 ± 3.7	13.8 ± 3.9	13.6 ± 3.9	16.7 ± 2.9	<0.001
Paternal education (years)	13.2 ± 3.5	12.9 ± 3.5	13.1 ± 3.9	15.6 ± 3.0	<0.001

Data shown as mean ± SD or n (%). CG, control group; TG1, test group 1 (1.5 g HMOs/L); TG2, test group 2 (1.5 g HMOs/L); HMG, human milk-fed group; HMOs, human milk oligosaccharides.

[a]P-values for overall group comparison are derived from one-way ANOVA or Pearson's chi-squared test. [b]For 9 infants in TG1 it was not known whether complementary foods were consumed or not by age 6 months.

Figures 3F,I), indicating that the five HMO formulas shifted the gut microbiome composition of both cesarean- and vaginally delivered infants toward that of vaginally delivered human milk-fed infants.

We compared abundances of predefined bacteria taxa (*Bifidobacterium* [including infant-type *Bifidobacterium* (sub)species], *Streptococcus*, *Lactobacillus*, Clostridia, and Peptostreptococcaceae; **Figure 4** and **Supplementary Figure 3**). The relative abundance of *Bifidobacterium* seemingly increased in TG1 and TG2 over 6 months, while in CG, it decreased between 3 and 6 months. Consequently, at 6 months of age, the relative abundance of *Bifidobacterium* was higher by ∼45% in TG1 and TG2 compared to CG ($P < 0.001$) and was similar to that in HMG ($P > 0.05$; **Figure 4A**). Separated by delivery mode, a similar pattern was observed, particularly in the cesarean-delivered infants (**Figures 4B,C**). Of the *Bifidobacterium* (sub)species showing statistical differences among formula groups, *Bifidobacterium longum* subsp. *infantis* (*B. infantis*) relative abundance at 3 and 6 months of age was higher in TG1 ($P < 0.0001$ and $P = 0.010$, respectively) and TG2 ($P = 0.016$ and $P = 0.083$, respectively) than in CG and approaching HMG. However, relative abundance of

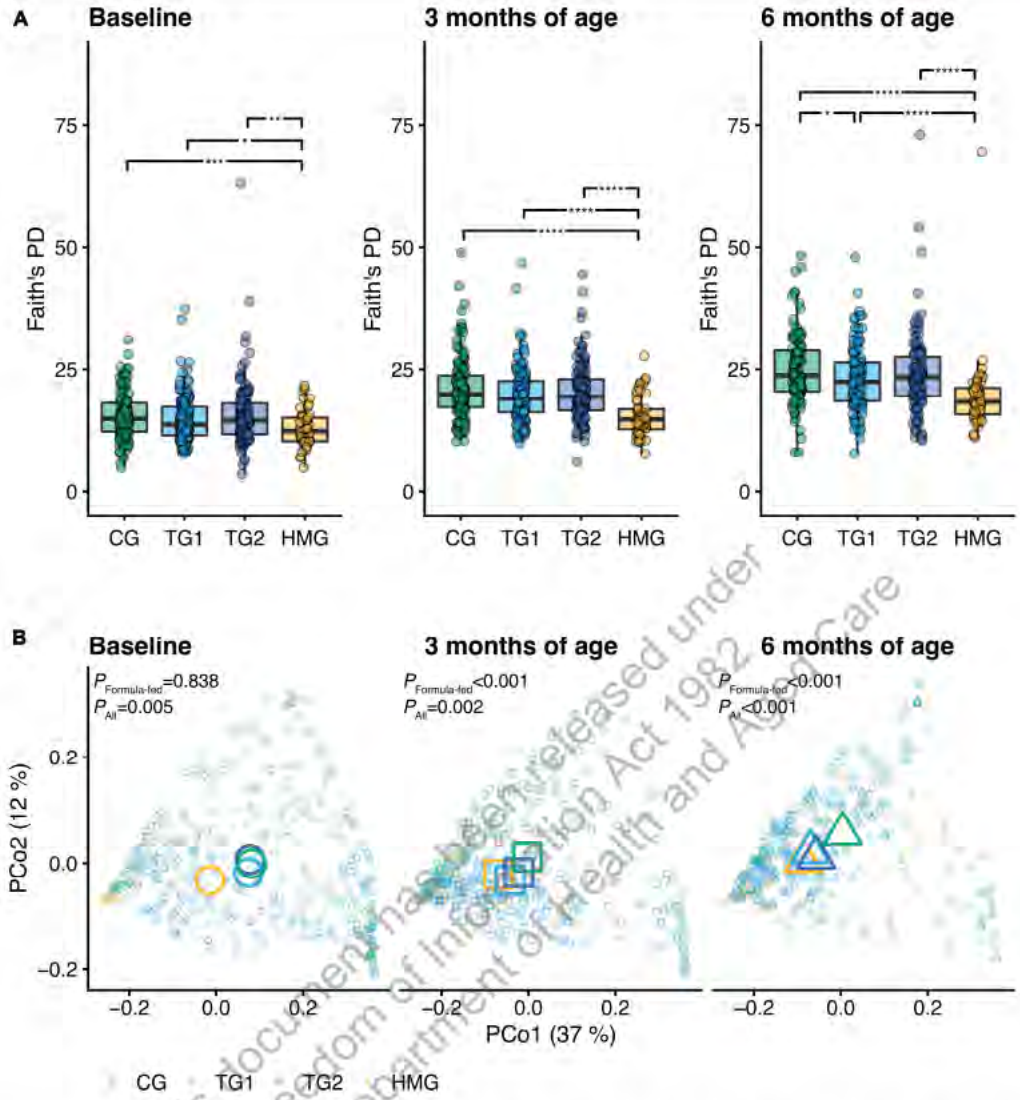

FIGURE 2 | (A) Alpha diversity (Faith's phylogenetic diversity) of the gut microbiota of the infants in the four feeding groups at each timepoint (baseline left, 3 months of age center, 6 months of age right). Box plots show the median and 25th and 75th percentiles with Tukey whiskers. Within each timepoint, all feeding groups were compared pairwise (Dunn's test), and significant differences are highlighted with significance bars. *P < 0.05, **P < 0.01, ***P < 0.001, ****P < 0.0001. **(B)** Principal coordinates analysis (PCoA) based on weighted UniFrac distance. Feeding groups are color-coded and faceted by timepoint. Individual data points are shown, with the mean (centroid) of each group indicated as a larger symbol. The x- and y-axis labels indicate the microbial variance explained by the first two principal coordinates. P-values for permutational multivariate analysis of variance (PERMANOVA) using feeding group as explanatory variable are shown for all infants and the subset of formula-fed infants at each visit. At baseline/3/6 month of age, CG, n = 135/135/111; TG1, n = 140/138/113; TG2, n = 136/140/117; HMG, n = 50/55/50. CG, control group; TG1, test group 1 (1.5 g HMOs/L); TG2, test group 2 (1.5 g HMOs/L); HMG, human milk-fed group; HMOs, human milk oligosaccharides.

B. infantis was also higher in TG1 than in CG at baseline (P = 0.006; **Figure 4D**). Relative abundance of infant-type *Bifidobacterium* species was higher in HMG than in CG at all timepoints (all P < 0.05). At 3 months, TG1 was higher than CG (P < 0.001), and at 6 months of age, both TG1 and TG2 were significantly higher than CG, while TG1 was indifferent compared to HMG (**Figure 4E**). At 6 months, abundances of *B. catenulatum* subsp. *kashiwanohense* and *B. pseudocatenulatum* were higher in TG2 than in CG and TG1 (P < 0.05; **Supplementary Figures 4E,H**). In addition, *B. dentium* abundance was significantly higher in TG2 than in CG at all three timepoints (**Supplementary Figure 4F**). At baseline, we did not observe any significant differences among the three formula-fed groups for Clostridia, *Lactobacillus*, Peptostreptococcaceae, and *Streptococcus* (all pairwise P > 0.05). At 3 and/or 6 months, the abundance of these taxa in TG1 and/or TG2 were significantly different from that of CG (P < 0.05) and approaching HMG (**Supplementary Figure 3**).

At baseline, the relative abundance and prevalence of toxigenic *Clostridioides (C.) difficile* were similar in the three formula-feeding groups (P > 0.05; **Figure 5A**). By contrast, at age 3 and 6 months, the relative abundances in TG1 and TG2

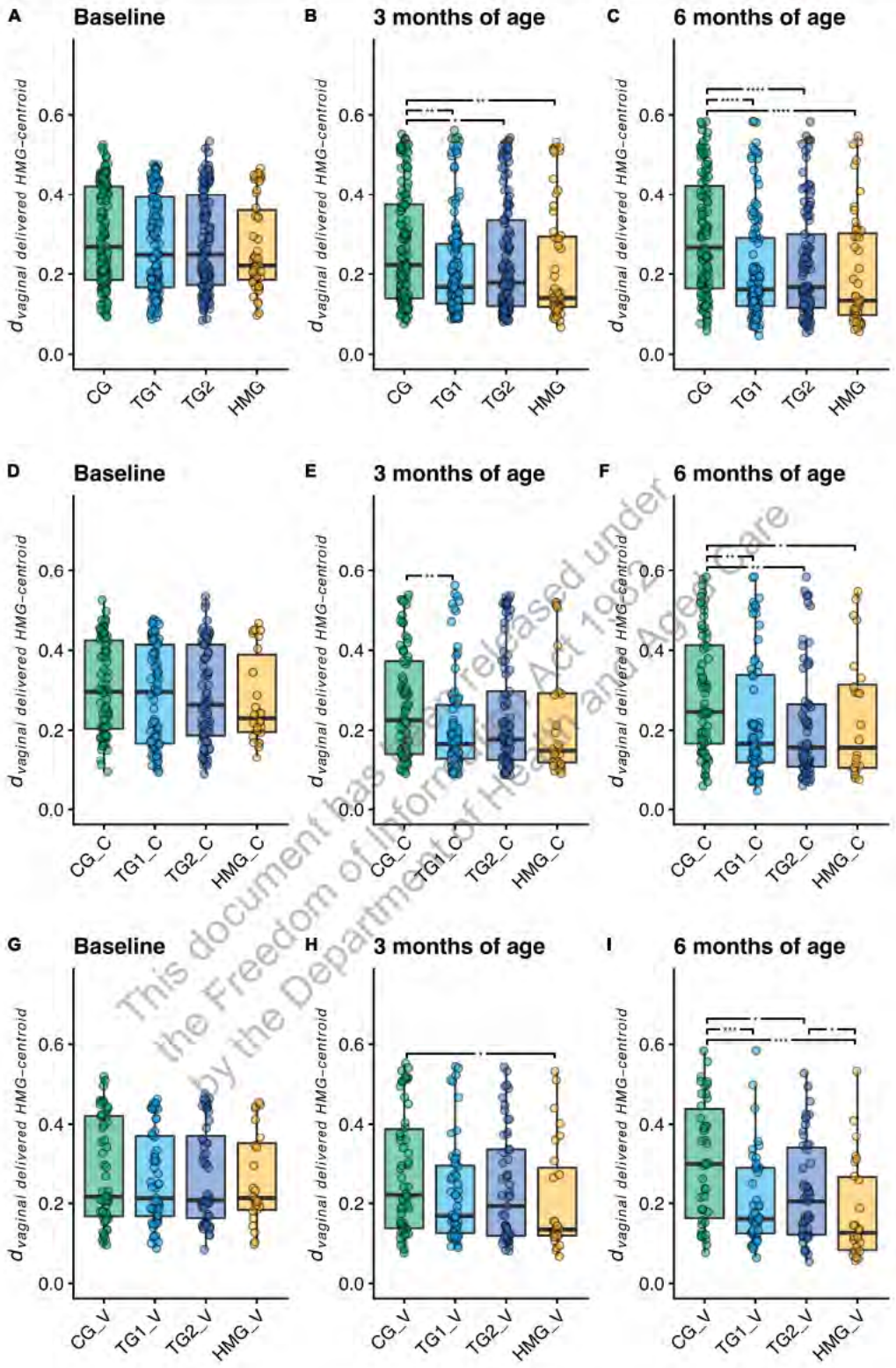

FIGURE 3 | Distance to the centroid of vaginally delivered HMG infants in principal coordinates analysis space of weighted UniFrac distance ($d_{vaginal\ delivered\ HMG-centroid}$) at each timepoint for all infants **(A–C)**, cesarean-delivered infants **(D–F**, indicated with "_C" in the labels), and vaginally delivered infants (**G–I**, indicated with "_V" in the labels). Box plots show the median and 25th and 75th percentiles with Tukey whiskers. Within each timepoint, all groups were compared pairwise with Mann–Whitney U tests, and significant differences are highlighted with significance bars. *P < 0.05, **P < 0.01, ***P < 0.001, ****P < 0.0001. At baseline/3/6 month of age, CG, n = 135/135/111; TG1, n = 140/138/113; TG2, n = 136/140/117; HMG, n = 50/55/50 for all infants **(A–C)**, CG,

(Continued)

FIGURE 3 | n = 79/77/69; TG1, n = 81/82/66; TG2, n = 80/85/66; HMG, n = 26/28/24 for cesarean-delivered infants **(D–F)**, CG, n = 56/58/42; TG1, n = 59/56/47; TG2, n = 56/55/51; HMG, n = 24/27/26 for vaginally delivered infants **(G–I)**. CG, control group; TG1, test group 1 (1.5 g HMOs/L); TG2, test group 2 (1.5 g HMOs/L); HMG, human milk-fed group; HMOs, human milk oligosaccharides.

were lower than those in CG by 75–85% (all $P < 0.05$) and comparable to HMG (**Figures 5B,C**). At age 3 months, the prevalence of toxigenic *C. difficile* trended to be lower in TG1 (6.5%) and TG2 (5.7%) than in CG (13.3%; $P \leq 0.069$). At 6 months, toxigenic *C. difficile* prevalence was lower in TG1 (10.6%) and TG2 (6.0%) than in CG (27.9%; $P \leq 0.001$) and comparable with HMG (10.0%; $P > 0.05$). Other pathogens, such as *Campylobacter jejuni*, *Campylobacter coli*, *Clostridium perfringens*, enteropathogenic *Escherichia coli*, enterotoxigenic *Escherichia coli*, *Klebsiella pneumoniae*, and *Salmonella enterica*, had low prevalence ($\leq$ 4 infants/feeding group) and were not investigated further.

Fecal Biomarkers

Adjusted mean concentrations of sIgA, AAT, and calprotectin at 3 and 6 months are shown in **Figure 6**. At 3 months, concentrations of sIgA in TG1 and TG2 were 53% ($P < 0.01$) and 43% ($P < 0.05$) higher than those in CG, respectively, and the difference persisted at 6 months for TG2 ($P < 0.05$). HMG had the highest sIgA concentration at both post-baseline timepoints compared to the formula-fed groups (all pairwise $P < 0.001$). AAT was lower in TG1 and TG2 than in CG at 3 months ($P < 0.05$). No significant difference was found at 6 months. The concentration of AAT in HMG was not statistically different from the formula-fed groups at either timepoint. Calprotectin tended to be lower in TG1 than in CG at 3 months ($P = 0.088$). At 6 months, calprotectin was lower in TG1 vs. CG ($P < 0.05$) and tended to be lower in HMG vs. CG ($P = 0.059$).

Fecal pH and Organic Acids

Fecal pH in the test groups was lower than that in CG at 3 and 6 months ($P < 0.05$; **Table 2**). At 6 months, HMG showed the lowest pH (all pairwise $P < 0.05$), and pH in TG2 was lower than in TG1 ($P < 0.05$). At both post-baseline timepoints, CG had a significantly lower concentration of lactate than the other groups (**Table 2**). At 6 months, HMG had the highest lactate concentration (all pairwise $P < 0.05$). The relative proportion of acetate to total SCFA at 3 and 6 months was lower in CG vs. test groups ($P < 0.01$, except CG vs. TG1 at 6 months $P = 0.059$) and highest in HMG (all pairwise $P < 0.001$). At 3 months, relative proportions of butyrate and isobutyrate were lower in TG1 and TG2 than in CG ($P < 0.05$) and similar as in HMG. At 6 months, a similar pattern was observed with HMG being lowest (all pairwise $P < 0.05$), but butyrate in TG1 was no longer different from CG and isobutyrate only trended to be lower in TG1 vs. CG ($P = 0.060$). At 3 and 6 months, the proportion of propionate was not significantly different in the formula-fed groups but was significantly lower in HMG. At 3 months, the relative proportion of isovalerate was significantly higher in CG than in TG1, TG2, and HMG. At 6 months, CG trended to be higher than TG1 ($P = 0.052$) and was higher than TG2 and HMG ($P < 0.001$). At 3 months, TG1 had significantly lower valerate proportion than CG and HMG. At 6 months, CG was significantly higher than TG1 and HMG, and TG2 was significantly higher than HMG.

DISCUSSION

To our knowledge, this is the first study investigating the effect of an infant formula with a specific blend of five HMOs on gut maturation, including microbiota composition and metabolism, as well as gut barrier and immune function. Our main findings are the ability of this specific HMO blend to drive the gut microbiota development of formula-fed infants directionally toward that of breastfed infants, including higher bifidobacteria and lower toxigenic *C. difficile* abundance, and to improve early-life intestinal immune response as indicated by the higher fecal sIgA concentration in the test groups vs. CG. Our results unveil important roles of the tested HMO blend in the development of the gut microbiome in early life. Given the importance the gut microbiome has in regulating and fine-tuning the development of the immune system, the tested HMO blend can potentially contribute beneficially to the short- and long-term health of formula-fed infants.

The HMO formulas impacted the gut microbiota composition as early as 3 months of age as indicated by beta diversity analysis. At 6-month age, gut microbiota modulating effects were even more distinct with some of the alpha-diversity indexes (richness and Shannon index at the genus level) being significantly lower in the test groups than in CG, with TG1 being no longer significantly different from HMG based on beta diversity analysis. Our data also show that the shift of the test groups toward the vaginally delivered HMG was observed irrespectively of the delivery mode, which is an interesting observation considering the reference role the vaginally delivered breastfed babies play in the interpretation of the gut microbiota findings.

The findings at 6 months suggest that HMOs play a crucial role in shaping the gut microbiome even after introduction of complementary foods and that the five-HMO blend promotes a human milk-fed alike bifidobacteria pattern beyond the exclusive formula-feeding period. *Bifidobacterium* species found in the gastrointestinal tract of infants are known to metabolize HMOs (37). A noteworthy difference in our study was the higher abundances of *B. infantis* in the test groups than in CG. These results indicate that *B. infantis* gains a competitive advantage in the presence of the five HMOs. *B. infantis* is expected to have the genetic makeup to use the dominant oligosaccharides (38), and several strains were shown to broadly metabolize HMOs like those used in this study (39, 40). Interestingly, the effects of the HMO-supplemented formula on the gut microbiota in cesarean- or vaginally born infants were similar, changing the microbiota toward the composition observed in vaginally born infants of HMG, including an increase in *Bifidobacterium*. This suggests that HMOs help correct some of the potential underlying

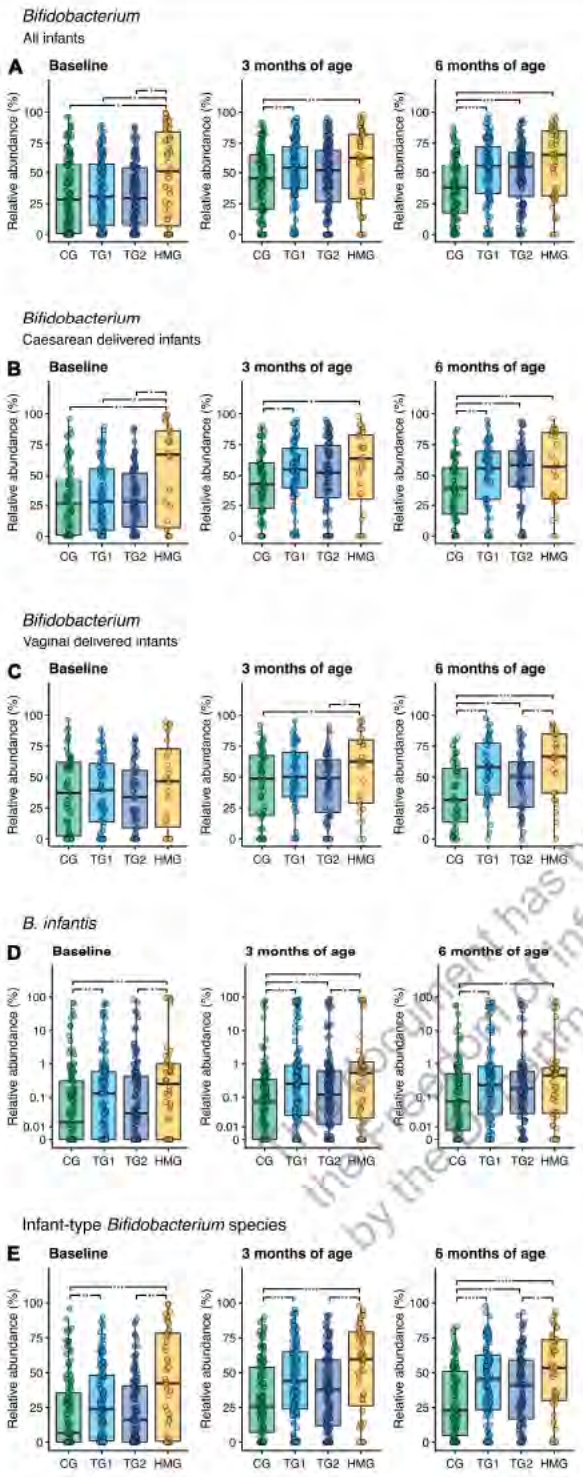

FIGURE 4 | Relative abundance of **(A)** *Bifidobacterium* including all infants, **(B)** *Bifidobacterium* in cesarean-delivered infants, **(C)** *Bifidobacterium* in vaginally delivered infants, **(D)** *Bifidobacterium longum* subsp. *infantis* (*B. infantis*), and **(E)** infant-type *Bifidobacterium* species in the four feeding groups at each timepoint (baseline left, 3 months of age center, 6 months of age right). Infant-type *Bifidobacterium* species is defined as the summarized relative abundance of *B. longum* subsp. *infantis*, *B. longum* subsp. *longum*, *B.*

(Continued)

FIGURE 4 | *bifidum*, and *B. breve* (36). Box plots show the median and 25th and 75th percentiles with Tukey whiskers. Relative abundance of B. infantis is plotted on a pseudo-logarithmic scale to display values spanning several orders of magnitude, as well as zeros. Within each timepoint, all feeding groups were compared pairwise (Dunn's test), and significant differences are highlighted with significance bars. *P < 0.05, **P < 0.01, ***P < 0.001, ****P < 0.0001. At baseline/3/6 month of age, CG, n = 135/135/111; TG1, n = 140/138/113; TG2, n = 136/140/117; HMG, n = 50/55/50 for all infants **(A,D,E)**, CG, n = 79/77/69; TG1, n = 81/82/66; TG2, n = 80/85/66; HMG, n = 26/28/24 for cesarean-delivered infants **(B)**, CG, n = 56/58/42; TG1, n = 59/56/47; TG2, n = 56/55/51; HMG, n = 24/27/26 for vaginally delivered infants **(C)**. CG, control group; TG1, test group 1 (1.5 g HMOs/L); TG2, test group 2 (1.5 g HMOs/L); HMG, human milk-fed group; HMOs, human milk oligosaccharides.

dysbiosis in cesarean-born delivered infants (41). A similar beneficial effect on dysbiotic gut microbiota in cesarean-born delivered infants has been reported for breastfeeding (41, 42). A previous study also found a bifidogenic effect in infants receiving formula with two HMOs (2′FL, LNnT) which was more pronounced in the cesarean-born infants. However, the study did not find any specific effect on *B. infantis* (24).

In our study, acetate proportion and lactate concentration were higher in the infants receiving the HMO formulas than those of CG. Since acetate and lactate are the main end-products of the bifidobacteria catabolism (43), our results can be explained by the increased growth of bifidobacteria in the test groups and possibly also by HMO-stimulated increased activity of enzymes involved in the metabolic pathways of bifidobacteria (44). On the other hand, we observed that proportions of butyrate, isobutyrate, or isovalerate were lower in the test groups and HMG than in CG, indicating a more diverse microbiota in CG, for example, butyrate is produced by *Bacteroides* and Firmicutes (e.g., *Clostridium*), but not by *Bifidobacterium* (45). Lactate and acetate play a vital role for the pH regulation in the colon (46), and the lower pH observed in the test groups in our study possibly contributed to the reduction in *C. difficile* in the test groups. Acetate might also have contributed directly to the lower relative abundance of *C. difficile* as results from an *in vivo* study indicate that acetate promotes innate host responses against *C. difficile* through coordinated action on neutrophils and group 3 innate lymphoid cells (47). A direct effect of the HMOs preventing epithelial adhesion of *C. difficile* by acting as decoy receptors might have been possible too; however, pre-clinical work suggests that the effect is rather indirect *via* gut microbiota modulation (48). Our findings about toxigenic C. *difficile* are of importance because they indicate that the five-HMO blend can reduce a risk factor for infectious diarrhea in formula-fed infants.

The intestinal immune response, gut barrier function/permeability, and the inflammatory signals in the gut are evolving during gut maturation. Fecal sIgA, a marker of intestinal immune response (49), was higher in TG1 and TG2 than in CG at 3 months, and the difference persisted in TG2 at 6 months. This may be linked to the increases in bifidobacteria, which have been shown to interact with human immune cells (50), and their surface-associated molecules and their metabolites may exert immunomodulatory functions (51, 52).

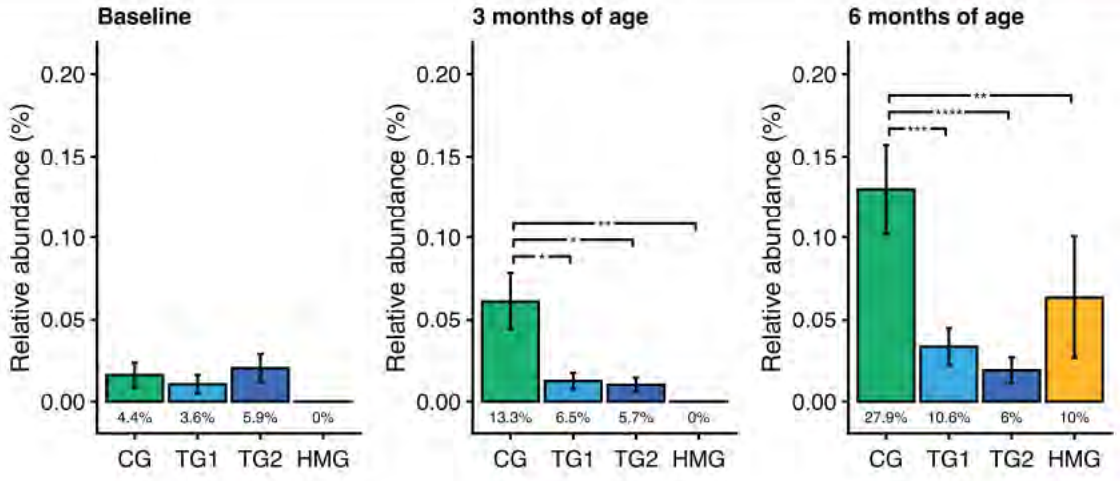

FIGURE 5 | Relative abundance of toxigenic *Clostridioides difficile* in the four feeding groups at each timepoint (baseline left, 3 months of age center, 6 months of age right). Bars show the mean relative abundance with error bars indicating the standard error. Prevalence for each group (percentage of infants with detectable levels of toxigenic *C. difficile*) is displayed below the bar. Within each timepoint, the relative abundance of *C. difficile* in all feeding groups were compared pairwise (Dunn's test), and significant differences are highlighted with significance bars. *$P < 0.05$, **$P < 0.01$, ***$P < 0.001$, ****$P < 0.0001$. At baseline/3/6 months of age, CG, n = 135/135/111; TG1, n = 140/138/113; TG2, n = 136/140/117; HMG, n = 50/55/50. CG, control group; TG1, test group 1 (1.5 g HMOs/L); TG2, test group 2 (1.5 g HMOs/L); HMG, human milk-fed group; HMOs, human milk oligosaccharides.

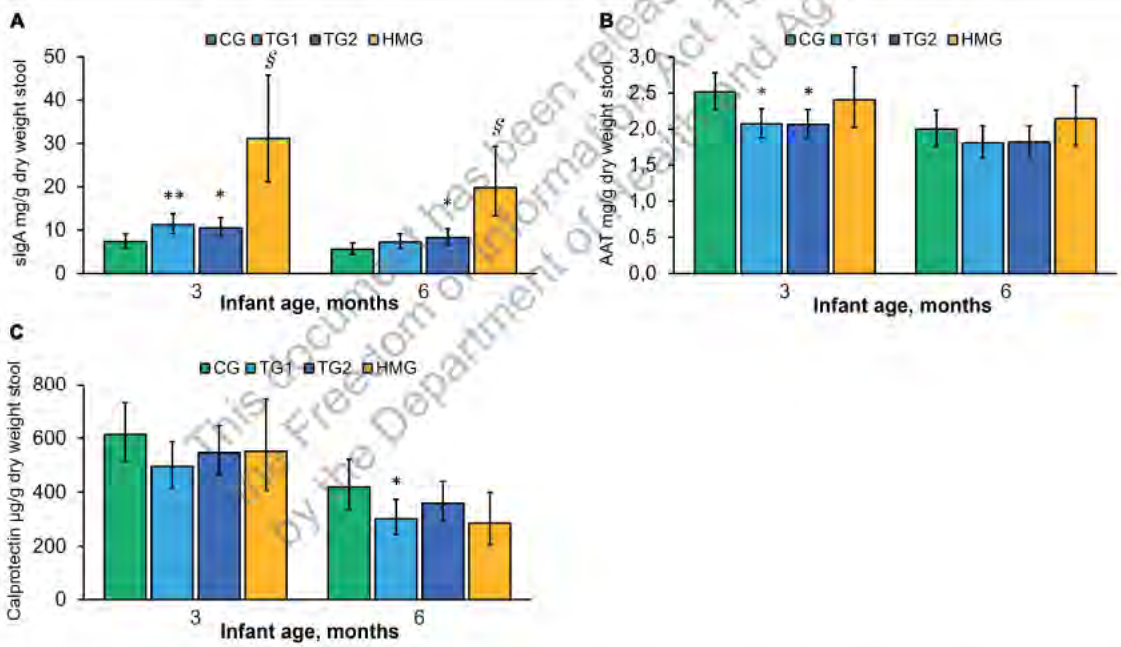

FIGURE 6 | Concentration of sIgA **(A)**, AAT **(B)**, and calprotectin **(C)** in the four feeding groups at 3 and 6 months of age. Data presented as adjusted means with the 95% CI as whiskers and expressed per gram fecal dry weight. Within each timepoint, all feeding groups were compared pairwise using ANCOVA models adjusted for baseline value of the measure of interest. *$P < 0.05$ vs. CG; **$P < 0.01$ vs. CG; § $P < 0.001$ vs. all formula groups. At 3/6 months of age, CG, n = 102/85; TG1, n = 110/90; TG2, n = 113/99; HMG, n = 35/37 for sIgA; CG, n = 102/85; TG1, n = 109/88; TG2, n = 112/99; HMG, n = 34/36 for AAT; CG, n = 102/85; TG1, n = 110/89; TG2, n = 113/99; HMG, n = 35/37 for calprotectin. AAT, alpha-1-antitrypsin; CG, control group; TG1, test group 1 (1.5 g HMOs/L); TG2, test group 2 (1.5 g HMOs/L); HMG, human milk-fed group; HMOs, human milk oligosaccharides; sIgA, secretory IgA.

Recently, Laursen and colleagues demonstrated that human milk-promoted *Bifidobacterium* species produce indole-3-lactate, a tryptophan metabolite, which may impact intestinal homeostasis and immune response in early life (36). In our study, test groups had significantly higher abundance of these breastmilk-promoted *Bifidobacterium* species, indicating that the five-HMO blend likely increases the production of some immunomodulatory metabolites in formula-fed infants. Furthermore, acetate has been

TABLE 2 | Fecal pH, total concentration of lactate, and relative proportion of individual short-chain fatty acids at 3 and 6 months of age.

	3 months				6 months			
	CG	**TG1**	**TG2**	**HMG**	**CG**	**TG1**	**TG2**	**HMG**
Fecal pH[1]	6.49[a] [6.30; 6.68]	6.05[b] [5.87; 6.24]	5.82[b] [5.63; 6.00]	5.95[b] [5.66; 6.24]	6.57[a] [6.34; 6.81]	6.14[b] [5.90; 6.37]	5.66[c] [5.44; 5.88]	5.19[d] [4.85; 5.52]
Lactate (umol/g)[1]	2.38[a] [1.69; 3.35]	4.64[b] [3.34; 6.44]	4.73[b] [3.41; 6.57]	4.63[b] [2.81; 7.63]	0.68[a] [0.44; 1.07]	1.98[b] [1.29; 3.04]	1.77[b] [1.18; 2.66]	4.58[c] [2.46; 8.53]
Acetate (%)[2]	77.1 (12.0)[a] 32.6; 98.4	81.8 (9.8)[b] 53.7; 99.4	81.2 (10.7)[b] 43.9; 99.1	89.2 (9.6)[c] 54.7; 99.3	75.3 (10.9)[a] 44.4; 94.3	77.4 (12.3)[a,b] 8.6; 99.5	79.4 (9.8)[b] 41.2; 97.5	86.9 (11.6)[c] 44.2; 98.7
Butyrate (%)[3]	2.76[a] [2.20; 3.47]	1.69[b] [1.32; 2.17]	1.94[b] [1.54; 2.43]	1.41[b] [1.00; 1.98]	3.73[a] [2.97; 4.70]	2.59[a,b] [1.93; 3.47]	2.47[b] [1.95; 3.13]	1.43[c] [0.94; 2.16]
Isobutyrate (%)[3]	0.66[a] [0.53; 0.83]	0.34[b] [0.27; 0.42]	0.32[b] [0.26; 0.40]	0.25[b] [0.19; 0.34]	0.80[a] [0.64; 1.01]	0.60[a] [0.47; 0.76]	0.37[b] [0.29; 0.47]	0.25[c] [0.17; 0.36]
Propionate (%)[3]	12.6[a] [11.0; 14.5]	10.4[a] [9.0; 12.0]	10.4[a] [8.9; 12.2]	3.7[b] [2.6; 5.3]	13.9[a] [12.1; 16.1]	12.1[a] [10.0; 14.6]	12.6[a] [11.1; 14.3]	5.7[b] [4.2; 7.7]
Isovalerate (%)[3]	0.53[a] [0.43; 0.66]	0.28[b] [0.23; 0.35]	0.28[b] [0.23; 0.33]	0.27[b] [0.21; 0.36]	0.58[a] [0.46; 0.73]	0.43[a] [0.34; 0.55]	0.29[b] [0.23; 0.36]	0.22[b] [0.17; 0.29]
Valerate (%)[2]	0.33 (0.91)[a] 0.02; 6.65	0.21 (0.48)[b] 0.02; 3.91	0.23 (0.79)[a,b] 0.03; 8.11	0.31 (0.41)[a] 0.05; 2.64	0.37 (0.72)[a] 0.04; 5.13	0.27 (0.70)[b,c] 0.02; 5.96	0.30 (0.60)[a,b] 0.03; 3.85	0.23 (0.37)[c] 0.04; 1.76

[1]*Values are adjusted means [95% confidence intervals]. For lactate, absolute concentrations in the feces based on dry matter are reported.*
[2]*Values shown are mean (SD); Min, Max for the relative proportion to total short-chain fatty acid concentration.*
[3]*Values shown are geometric means [95% confidence intervals] for the relative proportion to total short-chain fatty acid concentration.*
Values without a common superscript letter within one timepoint are significantly different from each other ($P < 0.05$ based on pairwise comparison using ANCOVA models adjusted for baseline value of the measure of interest or Wilcoxon test for valerate). At 3/6 month of age, CG, n = 127/101; TG1, n = 133/102; TG2, n = 135/113; HMG, n = 56/51 for fecal pH; CG, n = 115/89; TG1, n = 125/95; TG2, n = 125/105; HMG, n = 54/45 for lactate; CG, n = 114/81; TG1, n = 122/84; TG2, n = 119/98; HMG, n = 54/46 for acetate, butyrate, isobutyrate, propionate, isovalerate, and valerate. CG, control group; TG1, test group 1 (1.5 g HMOs/L); TG2, test group 2 (1.5 g HMOs/L); HMG, human milk-fed group; HMOs, human milk oligosaccharides.

shown to support T-cell-dependent intestinal IgA production in mice (53), and bifidobacteria-supplemented infant formula has been associated with increased fecal sIgA (54, 55). In addition to the sIgA produced by the B lymphocytes in the submucosal tissues, sIgA is also provided to infants *via* consumption of human milk (56), which is consistent with our finding that the HMG had a significantly higher sIgA concentration than the formula-fed groups. We observed that concentrations of AAT, a marker of intestinal permeability, were significantly lower in TG1 and TG2 than in CG at 3 months. In formula- and human milk-fed infants, AAT is known to decrease during infancy (57), and our results indicate that HMOs may contribute to this development in formula-fed infants in the first months after birth. HMG also showed the expected downward trend from 3 to 6 months, but AAT concentration was numerically higher at 6 months than that in the formula groups. This is likely due to AAT found in human milk which contributes to the overall measured concentrations but is not produced by the infant (58). We also found some indication that the HMO formulas contribute to the known decrease in the gut inflammation marker calprotectin in infants over time (59, 60). Together, our fecal biomarker results indicate that HMO-supplemented formula may be supportive of the infant intestinal immune development and gut barrier function.

Our study has several strengths. We had a substantial sample size with > 100 infants in the formula groups and > 50 in HMG. We used shotgun metagenomics which, compared with traditional 16S rRNA technique, provides more accurate and reliable profiling of bacterial (sub)species, allowing us to assess different *Bifidobacterium* (sub)species and to evaluate pathogenicity of species based on the presence of corresponding virulence genes (e.g., toxigenic *C. difficile*). To strengthen our assessment of the impact of the HMOs on infant gut physiology, we complemented our analysis with selected fecal metabolites and biomarkers. A limitation of our study is the lack of detailed data of complementary feeding after 4 months of age, which likely contributed to the gut maturation between 4 to 6 months of age. The available data show that most of the formula-fed infants have received complementary foods between 4 and 6 months of age (>90%), and there are unlikely any substantial differences in the types of consumed complementary foods among the formula-fed groups due to the randomization. Our study tested two different dosages of the five-HMO blend, but we did not observe any substantial dose-dependent response. Either the difference of 1 g HMOs per liter was not enough to detect potential dose-dependent responses or above 1.5 g HMOs per liter, there is a kind of a saturation effect for changes in microbiota and gut development using our HMO blend. The actual difference in HMOs actively used by the microbiota between the test groups might have been even smaller than 1 g per liter as the HMOs also act as decoy receptors and interact directly with the intestinal epithelium, and a small proportion is absorbed intact (7). The higher dose (TG2) doing slightly less good than TG1 for certain microbiota outcomes when compared to CG might therefore be due to data variability. Also, the proportion of HMOs not used by the microbiota might be increased with higher concentrations, which would be consistent with the findings for sIgA, where the direct interaction of HMOs with the intestinal mucosa might be

more important than the prebiotic effect and for which TG2 was numerically higher than TG1 at 6-month age and significantly different from CG. Further research is needed on potential dose-dependent effects of HMOs and HMO blends.

CONCLUSION

This multi-country, double-blinded trial demonstrates that the intestinal maturation of formula-fed infants can be beneficially modulated by an infant formula containing a specific blend of five HMOs. Consumption of HMO-supplemented formula in the first 6 months of life shifts the microbiota composition closer to that of infants receiving human milk. This includes a strong bifidogenic effect and less toxigenic *C. difficile*, which is expected to decrease the risk of diarrheal illness. The shift in the gut microbiota may mediate, to a certain extent, the effects that have been seen on intestinal immune response evidenced by the substantial increase in fecal sIgA. Supplementing infant formula with our blend of five HMOs is therefore a promising and efficacious approach to support the gut microbiome and gut barrier and immune maturation during early infancy of formula-fed infants.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors upon reasonable request, without undue reservation.

ETHICS STATEMENT

This study involving human participants was reviewed and approved by the Medical Research Council (Budapest, Hungary), the Bioethics Committee at the Regional Medical Chamber (Gdańsk, Poland) and the Ethics Committee of the Scientific Research at Medical University (Sofia, Bulgaria). Written informed consent to participate in this study was provided by the participants or their legal guardian/next of kin prior to enrollment.

5 HMO STUDY INVESTIGATOR CONSORTIUM

Members of the 5 HMO Study Investigator Consortium were Viktor Bauer, Dr. Kenessey Albert Hospital and Clinic, Balassagyarmat, Hungary; Malgorzata Arciszewska, Polyclinic of Gynecology and Obstetrics Arciszewscy, Bialystok, Poland; Maria Tarneva and Irina Popova, University Multiprofile Hospital for Active Treatment Deva Mariya—Neonatology, Burgas, Bulgaria; Svilen Dosev, Medical Center Prolet—Pediatrics department, Ruse, Bulgaria; Sirma Dimitrova, Medical Center Excelsior, Sofia, Bulgaria; Olga Nikolova, Multiprofile Hospital for Active Treatment Sveti Ivan Rilski, Kozloduy, Bulgaria; Marzena Nowak, Medical Center PROMED, Krakow, Poland; Magdalena Szuflinska-Sidorowicz, Medical Center Pratia Warszawa, Warszawa, Poland; Bartosz Korczowski, College of Medical Sciences, University of Rzeszów, Rzeszów, Poland; Rositsa Karcheva-Beloeva, Medical Center-1, Sevlievo, Bulgaria; Stefan Banov, Individual Practice for Specialized Medical Assistance, Stara Zagora, Bulgaria; Boguslawa Cimoszko, Primary Health Care Clinic Clinical Vitae, Gdansk, Poland; Wieslaw Olechowski, ALERGO-MED Specialist Medical Clinic, Tarnow, Poland; Robert Simko, Futurenest Clinical Research, Miskolc, Hungary; Zsuzsanna Tengelyi, Medical Center Clinexpert, Budapest, Hungary; Piotr Korbal, Dr. Jan Biziel's University Hospital No. 2, Bydgoszcz, Poland; Marta Zolnowska, Plejady Medical Center, Krakow, Poland; Anton Bilev, Medical Center Sveti Ivan Rilski Chudotvorets, Blagoevgrad, Bulgaria; Georgios Vasilopoulos, Center of Innovative Therapies, Piaseczno, Poland; Sylwia Korzynska, Medical Center Pratia Ostroleka, Ostroleka, Poland; István Laki, Kanizsai Dorottya Hospital, Nagykanizsa, Hungary; Margarita Koleva-Syarova, Diagnostic Consultative Center Ritam, Stara Zagora, Bulgaria; Toni Grigorov, Multiprofile Hospital for Active Treatment Sveti Georgi, Montana, Bulgaria; Steliyana Kraeva, Alitera Medical Centre, Sofia, Bulgaria; Éva Kovács, Family Pediatric Surgery/Babadoki Ltd., Szeged, Hungary; Rada Markova, Policlinic Bulgaria—Department of pediatrics; Sofia, Bulgaria; Grazyna Jasieniak-Pinis, Non-public Health Care Institution Specialist Clinics ATOPIA, Krakow, Poland; Katalin Fister Bugát Pál Hospital—Department of Pediatrics, Gyöngyös, Hungary; Tatyana Stoeva, Medical Center—Izgrev Ltd., Sofia, Bulgaria.

AUTHOR CONTRIBUTIONS

NS, BB, and CC designed the study. MB, IT, AK, and the 5 HMO Study Investigator Consortium conducted the experiments. HP, OL, AE, DG, NS, BB, and CC analyzed the data. HP, AE, NS, BB, and CC wrote the first draft. CC had primary responsibility for the final content. All authors read and approved the final version of the manuscript.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fnut.2022.920362/full#supplementary-material

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The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Attachment B

MAIF Complaints Committee's interpretation of the MAIF Agreement related to Health Care Professionals (Clause 7)

Overall Principles:

The purpose of this guidance is to support the interpretation of the Marketing in Australia of Infant Formulas: Manufacturers and Importers (MAIF) Agreement. This guidance does not replace the responsibility of the MAIF Complaints Committee to apply the MAIF Agreement objectively, using common sense in light of providing information and education, on a case-by-case basis.

These guidelines are to be read with the aim of the MAIF Agreement in mind and as an overarching principle: *to contribute to the safe and adequate nutrition for infants, by the protection and promotion of breastfeeding and by ensuring the proper use of breast milk substitutes, when they are necessary, on the basis of adequate information and through appropriate distribution.*

General Principles to Guide All Interactions with Health Care Professionals

All interactions between infant formula manufacturers and importers and health care professionals should:

- Be transparent and capable of public and professional scrutiny;
- Be carried out by representatives who are aware of the obligations of the MAIF Agreement
- Have the primary objective of providing scientific knowledge and/or providing factual information about the product

Relevant MAIF Agreement definitions

Health care system: governmental, non-governmental or private institutions engaged, directly or indirectly, in health care for mothers, infants and pregnant women and nurseries or childcare institutions. It also includes health workers in private practice. For the purposes of this document, the health care system does not include pharmacies or other retail outlets.

Health care professional: a professional or other appropriately trained person working in a component of the health care system, including pharmacists and voluntary workers.

Samples: Single or small quantities of infant formula provided without cost (WHO Code Article 3).

Information to health care professionals

1. To fulfill the aim of the MAIF Agreement, Clause 7b states that manufacturers and importers should provide information to health care professionals about their products. It is important that health care professionals have access to education on scientific and factual information about infant formulas and manufacturers and importers may play an important part in providing this information and education. Representatives of infant formula manufacturers and importers may request to visit health care professionals with the intent to educate them. It is up to health care professionals to decide whether they wish to see representatives of formula manufacturers.

2. Scientific information about infant formulas provided to health care professionals by manufacturers and importers should reflect the totality of the evidence, meaning that scientific information should reflect the current scientific knowledge comprehensively, not simply selective parts that can be used in a misleading way.

3. Scientific information should be supported by references to the scientific literature and the cited publication/s should be relevant and have been published in a peer reviewed journal. If this isn't possible, the manufacturer/importer, if requested, should be able to provide the MAIF Complaints Committee with supporting evidence and the rationale for supporting the scientific claims with that evidence.

4. The language used in scientific claims should reflect the quality and strength of the supporting reference(s)/ evidence and have regard to the GRADE framework, while noting limitations on randomisation in nutrition studies involving methods of infant feeding.

5. It is not considered a scientific or factual to claim that a product resembles, or is similar to, or is close to breast milk unless the specific nutrient that is similar to that found in breast milk is stated, and evidence is provided that satisfies the MAIF Complaints Committee that this specific claim is valid. Where these terms are used without a specific claim, the manufacturer may be considered to be implying equivalence with breast milk.

6. Information should not imply or create a belief that the infant formula product is equivalent or superior to breastfeeding.

7. The following should, where possible and relevant, be included in informational pieces when comparing breast milk with infant formula or ingredients of infant formula :
   a. the units of measurement
   b. the specific type of breast milk sample which is being compared
   c. the average or mean values and the standard deviation
   d. The references for the source of data should be provided.

Pictures on informational material or education material for health professionals

8. Information materials for health care professionals should not contain images, music or other devices that are likely to be attractive to young children, and therefore might lead to health care professionals putting them on display or giving them to children and caregivers. Examples might include toys or children's books..

9. Real infants depicted in a normal context do not necessarily idealise the use of infant formulas and may legitimately draw a health care professional's attention to information about an infant formula. However:
    - infants (with or without bottles) in fantasy or non-age-appropriate situations (e.g. stars, heavens, clouds, sitting up in school) should not be depicted because they may suggest formula-fed babies are in some way 'ahead of' or 'advanced' compared to breastfed babies;
    - infants with slogans over or adjacent to the pictures should not be used in such a way as to imply that the product is better than breast milk or idealise the use of infant formula; and
    - a picture of an apparently newly born baby should not be used to draw attention to information about infant formula. Breast milk is the best milk for babies up to 12 months old, but it is particularly valuable in the first few weeks of life when the baby is most vulnerable. Infant models for such pictures should be no younger than three months. Pictures of younger infants may be acceptable to draw attention to specialised products formulated for pre-term or low-birth weight babies for use under medical supervision.
    - A picture of a woman breastfeeding should not be used to draw attention to information about infant formula because it:
        - o May create an impression that the product is equivalent to breastfeeding;
        - o Appropriates the image of breastfeeding for the purpose of promoting a product; and
        - o May be considered a misleading way of gaining attention

    However, a picture of a woman breastfeeding may be used in the context of providing scientific and factual information about the benefits of breast milk and/or breastfeeding.

10. Cartoons and pictures of animals and toys do not necessarily idealise the use of infant formulas and therefore may be acceptable.

Inducements

- Low value items for professional use such as pens and papers (with the company name or logo only) may be handed out at a conference or provided to health

care professionals. Anything else intended or likely to be taken home may be considered an inducement and should not be left in a hospital ward or other health care facility.

- Competitions, included in information material for health professionals, which are clearly for the purpose of emphasising scientific and factual information only, may be acceptable. Such competitions should not be an inducement to promote infant formulas. The prize should be of low value not exceeding $100 and not excessive to be seen as an inducement.
- The provision of basic refreshments at informational/educational events is acceptable provided it is in association with a presentation that coincides with a mealtime and is not of a lavish nature.
- A professional diary that contains scientific and factual information about infant formula and conforms with the requirements of the MAIF Agreement, is not considered an inducement.

Distribution and provision of samples

11. Child care centres are not a setting in which professional evaluation of infant formula occurs, there is therefore no valid reason for manufacturers to give samples of infant formula to child care or day care centres.

Sponsorship

12. Infant formula manufacturers and importers sponsoring healthcare professional conferences, seminars or publications or displaying infant formula products or information at healthcare professional events is not a breach of the MAIF Agreement. It is up to the organisers to decide whether they wish to accept sponsorships or product displays.

However:

- any sponsorship of meetings, seminars or conferences should be declared. There should be no conditions which relate to the marketing of the sponsor's product or to restrictions on promotion of breastfeeding.
- the sponsor can recommend speakers based on relevant scientific expertise and may provide them with a brief. However, the speaker has sole editorial control over the content of their presentations. Sponsorship should not be conditional on the event organiser's acceptance of the recommended speaker and the event organiser/s maintain responsibility for final approval of speaker and topic.
- any donated conference materials may bear a company's logo but should not refer directly to an infant formula product.

USBs may also be used to provide access to educational websites (via web key for example) or to allow a healthcare professional to load clinical tools such as “health status” calculators or other instruments onto their computers.

It is acceptable to provide a healthcare professional with a Smartphone App, whether developed by the company or by a third party, as long as the App contains sufficient medical education. Guidance on advertisements used within these items, the PBS and the Product Information requirements can be found in Section 2.4.1 of these Guidelines.

For information on company branded items please refer to Table 8 and Sections 9.4.9 and 9.5.9 of these Guidelines.

FIGURE 15: COMPANY BRANDED ITEM OF MEDICAL EDUCATION (CONSISTENT WITH SECTION 4.1)

An anotomical model must include the company name and contact details

Section 2.7 Competitions

Competitions and quizzes may be run by member companies and are acceptable, but no prize or “gift” may be offered under any circumstances. Companies should ensure that requests for market research information, starter packs or products prescribed are separate and distinguishable from company run competitions.

Sponsorship of educational events at which third parties or conference organisers run competitions with prizes are acceptable, where the sponsorship is provided to support the educational content/activity. Examples of such activities would include, but are not limited to;

- “passport” activities that take place in trade display areas during an international or national congress;
- competitions published in medical/scientific journals where member company advertising may appear; and
- member company financial contributions to poster competitions held and judged by medical/scientific societies.

Companies should ensure that sponsorship funding is allocated for educational content or facilitation of such at smaller events, especially where the company is a sole sponsor. Sponsoring companies are ultimately responsible for ensuring that their financial contributions do not contribute to unacceptable components such as competition prizes or “gifts”.

Attachment D

MAIF Complaints Committee's interpretation of the MAIF Agreement related to electronic media marketing activity

Overall Principles

1. The purpose of these guidelines is to support the interpretation of the MAIF Agreement. This guidance does not replace the responsibility of the MAIF Complaints Committee to apply the MAIF Agreement objectively, using common sense in light of the context of the website, on a case by case basis.
2. These guidelines are to be read with the aim of the MAIF Agreement in mind and as an overarching principle: that is, to contribute to the safe and adequate nutrition for infants, by the protection and promotion of breastfeeding and by ensuring the proper use of breast milk substitutes, when they are necessary, on the basis of adequate information and through appropriate marketing and distribution.

Consumer-based websites

3. Prior to a consumer accessing information about infant formula on a manufacturer website, manufacturers should display to the consumer the information required by clauses 4(a) and 4(b) (Important Notice information). This display should include a click-through acknowledgement by the consumer that the consumer has read and understood the information. The display should be provided at least once per day for each consumer who accesses the site on multiple occasions.
4. A tab or link labelled 'Breastfeeding is Best', 'Benefits of Breast Milk' or similar, which links to the Important Notice information, should be included on each page of a website which provides information about an infant formula product. The tab/link should be included on the navigation toolbar of each web page or another equally prominent location.
5. The inclusion of product information about infant formula, including a description and pack shots, on a website is acceptable, provided the above guidelines 3 and 4 of this document are followed and:
    - the product information is the same as the information on the label of the product (for example: ingredient listing, nutritional profile and nutrition information);
    - any additional information provided is factual in nature and intended to provide sufficient information to help consumers to make an informed choice as to the specific nature of the infant formula; and
    - product logos are not displayed independently of pack shots.

Frequently Asked Questions

6. FAQ pages on websites are an important means of providing information regarding formulas to consumers, and assisting consumers to differentiate between different types of formula.
   Any FAQ pages relating to infant formula should commence with a statement as to why breastfeeding is best. This can be in the form of a statement at the top of the page, or an initial question and answer.

Other electronic communications and social media

7. In accordance with these guidelines, manufacturers and importers should adopt reasonable measures, to monitor and manage social media forums and other electronic platforms which are within their control to ensure they comply with the MAIF Agreement. Manufacturers and importers must not conduct any paid influencer activity for their infant formula products.
8. Manufacturers and importers should not initiate discussion or actively provide information about infant formula via social media forums and other electronic forums. However it is recognised that manufacturers and importers cannot control postings by consumers or third parties on such forums which are not under their control and are therefore entitled to respond to issues or questions raised provided:
   - the question is directed to the manufacturer or the issue requires a corrective or clarifying statement;
   - the response is in the same forum;
   - the response is in line with guideline 5 above and, unless the context otherwise requires, limited to the matters raised by the consumer or third party post;
   - if a question relates to a health condition, the consumer is directed to speak to a healthcare professional; and
   - includes a statement to the effect that breastfeeding is best for babies, which links to the Important Notice Information on the manufacturer's website.
9. Electronic mailings to consumers (such as e-newsletters) should only include information about infant formula which is otherwise permitted under the MAIF Agreement (for example, an announcement about change of availability). Where appropriate, the relevant communication should include the Important Notice information.
10. Manufacturers are entitled to initiate communication to consumers via social media forums and other electronic platforms on urgent health and safety matters provided the communication is limited to the health and safety matter.

Guidance on regulatory measures aimed at restricting digital marketing of breast-milk substitutes

World Health Organization

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Contents

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Terminology

For the purposes of this guidance, the following terms are used as in the Code.

Breast-milk substitutes are any food being marketed or otherwise represented to be suitable for use as a partial or total replacement of breast milk, whether or not suitable for that purpose, including any milks (or products that could be used to replace milk, such as plant-based milks), in either liquid or powdered form, that are specifically marketed for feeding infants and young children up to the age of 3 years (including follow-up formula and growing-up milks) *(2,10,11).*

Cross-promotion (also called "brand crossover promotion", "line extension" or "brand stretching") is a form of marketing promotion where customers of one product or service are targeted by the promotion of a related product. This can include packaging, branding and labelling of a product to closely resemble that of another (also known as "brand extension", "line extension" or "brand family"). In this context, it can also refer to use of particular promotional activities for one product and/or promotion of that product in particular settings to promote another product *(10,11).*

Distributors are persons, corporations or any other entities in the public or private sector engaged in the business of *marketing* at the wholesale or retail level of a product within the scope of the Code *(13).*

Foods for infants and young children means all commercially produced food or beverage products (including complementary foods) that are specifically marketed as suitable for feeding infants and children from six months up to 36 months of age.

Health care system means governmental, non-governmental or private institutions or organizations engaged, directly or indirectly, in health care for mothers, infants and pregnant women and nurseries or child-care institutions. It also includes health workers in private practice. For the purposes of the Code, the health care system does not include pharmacies or other established sales outlets *(10,11,13).*

Health worker means a person working in a component of such a health care system, whether professional or non-professional, including voluntary unpaid workers *(13).*

Manufacturers means corporations or any other entities in the public or private sector engaged in the business or function (whether directly or through an agent or through an entity controlled by or under contract with it) of manufacturing a product *(13).*

Marketing means promotion, distribution, selling, advertising, public relations and information services *(13).*

Promotion includes the communication of messages that are

designed to persuade or encourage the purchase or consumption of a product or raise awareness of a brand. Promotional messages may be communicated through traditional mass communication channels, the internet and other marketing media using a variety of promotional methods. In addition to promotion techniques aimed directly at consumers, measures to promote products to health workers or to consumers through other intermediaries are included. There does not have to be a reference to a brand name of a product for the activity to be considered as advertising or promotion *(10,11).*

In addition, the terms listed below are used as described for the purpose of this guidance.

Digital environments are the operational or information technology systems, networks, internet-enabled *applications*, devices and/or data contained within such systems and networks and any other related digital system. These include, but are not limited to, social media, websites, email services, text or voice or image or video messaging services, streaming services, search engines, eCommerce platforms, peer commerce and smartphone applications.

Digital marketing means *marketing* conducted or disseminated in digital environments and/or facilitated by digital technologies.

Digital marketing value chain means the full range of activities involved in producing and distributing digital marketing content. Actors involved in these activities typically include content producers, publishers, hosts, navigators and access providers *(14).*

Regulatory measures are actions taken by governments, as appropriate to their legislative frameworks, including laws (legislation), decrees, rules and regulations, compliance with which is mandatory and enforceable by an authority or agent empowered to do so. Voluntary measures are not regulatory measures and are not suitable for restricting marketing of breast-milk substitutes *(15, 16).*

Sponsorship includes any form of contribution made with the aim, effect or likely effect of increasing the recognition, recommendation or appeal of commercial foods or drinks for infants and young children, including formula milks for children up to 36 months, or their consumption, either directly or indirectly *(17)*.

Background

Recognizing the vulnerability of infants in the early months of life, the health risks introduced by the unnecessary and improper use of breast-milk substitutes, and the impact of the promotion of breast-milk substitutes on breastfeeding practices, Member States agreed that the marketing of breast-milk substitutes requires special treatment, which makes usual marketing practices unsuitable for these products *(2).* In 1981, the World Health Assembly adopted the Code to prohibit all forms of promotion of breast-milk substitutes.

The United Nations Commission on the Rights of the Child recognizes that governments have a duty to safeguard children's right to the enjoyment of the highest attainable standard of health *(3),* and that this duty confers upon them an obligation to implement and enforce the Code, noting, "States are required to introduce into domestic law, implement and enforce internationally agreed standards concerning children's right to health including the international Code of Marketing of Breast-milk Substitutes and the relevant subsequent World Health Assembly resolutions" *(4).* This instrument also recognizes that manufacturers and distributors also have an obligation to comply with the International Code of Marketing of Breast-milk Substitutes and its subsequent World Health Assembly resolutions *(5).*

The Convention on the Elimination of All forms of Discrimination Against Women *(6)* recognizes that governments have a duty to safeguard women's right to health, including by ensuring effective regulation of the marketing of breast-milk substitutes and the implementation and monitoring of the International Code of Marketing of Breast-milk Substitutes *(7).*

Most WHO Member States have taken steps to implement the Code by adopting legal measures to implement at least some of its provisions. Yet, few countries have adopted legal measures closely aligned with the provisions of the Code and enforcement of legal measures that have been adopted remains weak *(8).* Regulatory measures aimed at restricting digital marketing of breast-milk substitutes will be most effective in the context of comprehensive implementation of the Code (Mathiessen J, Vasic M, Zhu, N, University of Sydney Health Law Centre for the Pacific Community (SPC) Public Health Division, unpublished report, 2022). Comprehensive implementation of the Code means enacting and enforcing legal measures closely aligned with its scope and provisions, including its subsequent resolutions.

A comprehensive review of evidence describing the scope and impact of the promotion of breast-milk substitutes in digital environments was provided to the Seventy-fifth World Health Assembly. The WHO report on the scope and impact of digital marketing strategies for promoting breast-milk substitutes noted that digital environments are fast becoming the predominant source of exposure to promotion of breast-milk substitutes globally, digital marketing amplifies the reach and power of advertising and other forms of promotion in digital environments, and exposure to digital marketing increases the purchase and use of breast-milk substitutes *(9).*

Scope

This guidance applies to the digital marketing of products within the scope of the Code and to foods for infants and young children that are not breast-milk substitutes *(2,10,11)*. Products within the scope of the Code include breast-milk substitutes, including infant formula and other types of milks or products that could be used to replace milk, such as fortified plant-based milks. These can be in either a liquid or powder form specifically marketed for feeding infants and young children up to the age of three years, including follow-up formula and growing-up milks, any foods that are marketed or otherwise represented as being suitable for infants less than six months or as a partial or total replacement for breast milk (whether or not suitable for that purpose), including bottle-fed complementary foods, feeding bottles and teats. Foods for infants and young children are defined as all commercially produced food or beverage products (including complementary foods) that are specifically marketed as suitable for feeding infants and children from six months up to 36 months of age.

Digital marketing involves a broader range of actors than those involved in traditional marketing practices. Applying the Code to digital environments requires the development of specific implementation mechanisms, coordination across a broader set of government bodies, and the establishment of specific legal duties on the range of entities involved in the digital marketing value chain. These entities may include, but are not limited to, data management platforms, content creators (including influencers), internet service providers (known as ISPs), supply side platforms, demand side platforms, agency holding companies, social media platform providers, search engine providers, online retailers, streaming services, application owners and gaming service providers.

Humanitarian emergencies amplify health risks associated with inappropriate infant and young child feeding. Yet, the marketing of infant feeding products typically increases during these crises. The recommendations presented in this guidance apply to digital marketing during humanitarian and emergency contexts (*12*).

Digital marketing practices are diverse and constantly evolving. Therefore, examples given in this document should not be considered to be an exhaustive list of practices that should be subject to regulation.

This guidance recognizes that national regulatory environments vary and effective implementation mechanisms will adapt to country contexts and regulatory frameworks

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Purpose

The purpose of this guidance is to provide support to World Health Organization (WHO) Member States for developing and applying regulatory measures aimed at restricting digital marketing of products that fall within the scope of the International Code of Marketing of Breast-milk Substitutes and other subsequent relevant resolutions of the World Health Assembly (hereafter collectively referred to as "the Code") by applying the Code to digital environments in response to a request from the Seventy-fifth World Health Assembly in 2022 *(1).*

Methodology

To develop this report WHO assembled a steering committee from across WHO departments to decide upon scope, methodology and process. WHO solicited subject matter experts in public health law and regulation, digital marketing social science, epidemiology, marketing, global health, nutrition, psychology and consumer behaviour, human rights law, Code monitoring and implementation policy to serve on a technical advisory group (TAG). TAG members were drawn from all WHO regions. All members were required to complete the WHO declaration of interest. The WHO secretariat assessed declarations and excluded experts with material conflicts. Following an initial consultation meeting, at which the TAG advised on proposed scope and, the TAG met every three weeks for nine months to develop the overall approach, identify potential sources of evidence, discuss priority country actions, and review draft recommendations.

The TAG examined several sources of evidence, including the WHO report on Scope and impact of digital marketing strategies for promoting breast-milk substitutes, a review of relevant previous WHO recommendations, a comparative legal review on restricting digital marketing of unhealthy products, and qualitative research on technical and legal considerations for regulating the digital marketing of breast-milk substitutes.

WHO received comments through an online public consultation. A total of 65 submissions were carefully considered and the document amended where appropriate.

Recommendations

Recommendation 1

Member States should ensure that regulatory measures effectively prohibit the promotion of products within the scope of the Code, including brand promotion, across all channels and media, including digital media.

Recommendation 1.1. Regulatory measures should prohibit the use of digital marketing tools for the promotion of products within the scope of the Code, including, but not limited to, the following activities:

i. providing or disseminating any promotional content including advertising on social media platforms, streaming platforms, video-sharing platforms, gaming platforms or search engine platforms; in games, podcasts or video content; through websites, display advertisements, banner advertisements, pop-up advertisements, search engine advertising, dark posts, influencer marketing, affiliate marketing, email marketing, and other events hosted online or facilitated by digital technologies;

ii. establishing or participating in online social or support groups or communities, including baby clubs, parents' clubs, social or support groups for pregnant women or parents, whether these are visible to non-participants or not;

iii. offering or providing gifts, discounts or product samples directly or by providing a link or code that can be used to obtain a gift, discount or sample;

iv. providing or promoting software applications (apps), entertainment services or games aimed at pregnant women, parents, children or health workers;

v. soliciting (including by offering material or other incentives or inviting consumers to enter a competition or prize draw), publishing, sharing, commenting on or boosting user-generated content including product testimonials or reviews, static images, text or audio-visual content;

vi. encouraging or enabling consumers to share, react or comment on marketing content;

vii. product placements, including shoppable content (that consumers can click to make a purchase) in social media, audio or video-sharing platforms, games, gaming platforms, apps or other digital media;

viii. any other digital marketing practices, including cross-promotions, used to promote products within the scope of the Code, or to establish relationships between consumers and manufacturers or distributors of products within the scope of the Code or their brands.

Recommendation 1.2. Regulatory measures should prohibit the display of any images of a product label that does not satisfy the relevant provisions of the Code (particularly Article 9 of the International Code of Marketing of Breast-milk Substitutes, WHA58.32, WHA61.20, WHA63.23 and WHA69.9) in any information, educational materials, materials, or any other content in the digital environment.

Recommendation 1.3. Regulatory measures should prohibit manufacturers and distributors of products within the scope of the Code from contacting or seeking or soliciting direct or indirect contact with pregnant women, parents or caregivers of infants and young children in digital environments.

Recommendation 1.4. Regulatory measures should prohibit manufacturers of products within the scope of the Code or any entities acting on their behalf, acting directly or indirectly, from offering or providing advice, information (other than product information that is required to be provided by law) or education about infant and young child care, nutrition and feeding, maternal nutrition, pregnancy, child development, health and wellbeing or parenting, as static, dynamic or interactive content in digital environments, including, but not limited to, through e-learning courses, chat and messaging services, commenting on content posted on webinars, chatbots or other tools powered by artificial intelligence. This should include prohibiting offering or providing financial or other incentives to other entities for these purposes. Note that nothing in this paragraph should prevent manufacturers and distributors from providing product information that is required to be provided by law.

Recommendation 2

Regulatory measures should prohibit the promotion of products within the scope of the Code, or their brands, through health care systems and health professional associations using digital technologies.

Recommendation 2.1. Regulatory measures should prohibit the promotion of products within the scope of the Code or their brands in health care systems' digital presences (including websites, smartphone apps, online portals and social media accounts), websites and other digital presences.

Recommendation 2.2. Regulatory measures should prohibit manufacturers and distributors of products within the scope of the Code from offering or providing financial or material inducements to health workers to endorse a product or brand or provide professional advice or any other content to pregnant women, parents and caregivers of infants and young children in the digital environment.

Recommendation 2.3: Regulatory measures should prohibit the sponsorship of online meetings of health professionals and scientific meetings, including webinars, e-learning courses and information dissemination through online scientific communications, including advertising in digital medical journals and on e-learning platforms by manufacturers and distributors of products within the scope of the Code or foods for infants and young children *(10,11).*

Recommendation 3

Regulatory measures should prohibit the promotion of products within the scope of the Code and their brands at point-of-sale in digital environments, in alignment with the Code provisions on point-of-sale promotions, information and education and labelling.

Recommendation 3.1. Regulatory measures should prescribe the content, including product descriptions, permitted to be displayed for products within the scope of the Code at point-of-sale in digital environments. This should be limited to content required for a checkout process that facilitates purchase, a factual description of the product, labelling information consistent with provisions of the Code, including those articulated in Article 9 of the International Code of Marketing of Breast-milk Substitutes, resolution WHA61.20 and any other information required by food safety standards and national law.

Recommendation 3.2. Regulatory measures should prohibit the use of text and imagery at the point-of-sale in digital environments as described in Article 9.2 of the International Code of Marketing of Breast-milk Substitutes (WHA34.22), resolutions WHA58.32(2), WHA63.23(4), WHA69.9(2) and any other text that is not required to be provided by law. These prohibitions should apply to all point-of-sale promotions including, but not limited to, product recommendations, images or depictions of products or their labels, any other text or images, audio, video or pop-up content, in digital environments.

Recommendation 3.3. Regulatory measures should prohibit promotions described in Article 5 of the Code in digital point-of-sale environments.

Recommendation 4

Member States should prohibit inappropriate promotion of foods for infants and young children that are not breast-milk substitutes in digital environments *(10)*.

Recommendation 4.1. Regulatory measures should prohibit promotion of foods for infants and young children in digital environments that:

i. do not meet all the relevant national, regional and global standards for composition, safety, quality and nutrient levels and are in line with national dietary guidelines in digital environments;

ii. are marketed as suitable for infants less than six months of age;

Recommendation 4.2. Regulatory measures should prohibit any promotions of a food for infants and young children in digital environments that:

i. include any image, text or other representation that is likely to undermine or discourage breastfeeding, that makes a comparison to breast milk, or that suggests the product is nearly equivalent or superior to breast milk;

ii. recommend or promote bottle-feeding;

iii. conveys an endorsement or anything that may be construed as an endorsement by a professional or other body, unless this has been specifically approved by the relevant national, regional or international regulatory authority;

iv. include an image, text or other representation that might suggest use

for infants less than six months of age, including references to milestones and stages;

v. is presented in packaging that is similar to those used for breast-milk substitutes, including, but not limited to, using similar colour schemes, designs, names, slogans and mascots other than the company name and logo.

Recommendation 4.3. Regulatory measures should require that any promotion of a food for infants and young children in digital environments includes statements on the importance of continued breastfeeding for up to 2 years or beyond and of not introducing complementary feeding before six months of age.

Recommendation 5

Member States should confer legal duties of compliance to monitor and take immediate action to prevent or remedy prohibited marketing on entities along the digital marketing value chain.

Recommendation 5.1. Regulatory measures should identify actors involved in the digital marketing value chain and assign specific duties that are proportionate to those entities' control over the creation, publication, distribution or removal of non-compliant content and as appropriate in the country context. Duties may include identifying, monitoring and reporting prohibited marketing, content moderation, removing, filtering or blocking prohibited content. Each of these duties may be conferred upon more than one entity in the digital marketing value chain and each of those actors should be sanctioned for failing to comply with duties conferred to them.

Recommendation 6

Regulatory measures should identify government agencies responsible for implementation, monitoring and enforcement, including in digital environments, establish mechanisms for inter-agency collaboration, allocate adequate resources and establish powers necessary for discharging these duties.

Recommendation 6.1 Government agencies responsible for the Code and the Guidance on Ending Inappropriate Promotion of Foods for Infants and Young Children should be entirely independent of industry funding.

Recommendation 7

Member States should strengthen monitoring systems for detecting prohibited marketing in the digital environment, including by:

i. requiring entities in the digital marketing value chain to monitor and report the actions they have taken to moderate, block, filter or immediately remove prohibited marketing and ensure compliance with regulatory measures to specified government agencies;

ii. establishing notification mechanisms for individuals and civil society organizations and commercial entities to report non-compliant digital marketing to specified government agencies;

iii. conferring on individuals and civil society organizations the right to bring complaints before the courts; and

iv. using digital technologies, such as social media intelligence platforms, screen-capture software, traffic analysis or artificial intelligence tools to identify potentially non-compliant digital marketing for investigation and enforcement by specified government agencies

Recommendation 8

Member States should enforce their regulatory measures, including in digital environments, by applying effective, proportionate, dissuasive sanctions for non-compliance.

Recommendation 8.1. Regulatory measures should specify sanctions that correspond with, and are proportionate to, the responsible actors' duties of compliance.

Recommendation 8.2. Regulatory measures should establish a range of sanctions that are sufficient to deter all types of violations, proportional to the nature and seriousness of the violation and increase for repeat violations. Sanctions refer to penalties under domestic law and may include criminal and administrative or statutory penalties, financial penalties and fines, non-financial penalties, such as restrictions on licensing, product recalls, and corrective actions such as counter-advertising campaigns to correct misleading claims, among others.

Recommendation 9

Member States should exercise their jurisdiction to ensure that regulatory measures can be enforced against manufacturers and distributors of products within the scope of the Code and foods for infants and young children, and other actors across the digital marketing value chain, for digital marketing that crosses into or out of their countries and does not comply with regulatory measures.

Recommendation 9.1. Manufacturers, distributors, and other entities acting across the digital marketing value chain should be held liable for prohibited content that enters Member States' territories including, for example, by:

i. establishing licensing mechanisms that include requirements for compliance on entities that distribute or generate content that is made available within the jurisdiction;

ii. establishing legal obligations on domestic distributors of products within the scope of the Code for verification of supplier compliance with marketing regulations and strict liability for failure;

iii. requiring such entities that do business or provide services in their countries to maintain a domestic presence against which enforcement can be effected for breaches of regulatory measures.

Recommendation 9.2. Member States should prohibit their nationals and anyone acting within their territories from promoting products within the scope of the Code and foods for infants and young children, outside their borders across all channels and media, including digital marketing.

Recommendation 9.3. Member States should facilitate enforcement cooperation including, for example, through:

i. domestic legislation that recognises and enforces foreign judgments;

ii. domestic legislation that authorises local authorities to provide evidence to, and conduct investigations to assist, foreign enforcement agencies in order to prevent unlawful marketing being made available within their territories;

iii. establishing or effecting memoranda of understanding aimed at strengthening cooperation for protecting consumers from harmful or unlawful marketing;

iv. establishing or effecting bilateral and/or multilateral agreements on trade and/or enforcement;

v. establishing or engaging in regional networks for the purpose of enforcement cooperation *(18).*

Recommendation 10

All entities along the digital marketing value chain and in health care systems should ensure that their marketing practices conform to the Code in digital environments, irrespective of any regulatory measures implemented at national and subnational levels.

Recommendation 11

Member States should monitor developments in digital technologies and their impact on the marketing of products within the scope of the Code and foods for infants and young children, and adapt regulatory measures to capture new digital technologies, channels or marketing practices.

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Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Advertising therapeutic goods on social media

This guidance aims to help advertisers apply the legislative requirements for advertising therapeutic goods on social media platforms.

Published: 31 March 2022

On this page

Purpose

This guidance is designed to help advertisers apply the legislative requirements for advertising therapeutic goods when advertising on social media platforms.

Legislation

Therapeutic Goods Amendment (Therapeutic Goods Advertising Code) Instrume (No. 4) 2021

Therapeutic Goods Act 1989

About the TGA

The Therapeutic Goods Administration (TGA) is Australia's regulator of therapeutic goods including medicines and medical devices. The TGA is responsible for ensuring the safety, efficacy and timely availability of therapeutic goods.

To find out more about the TGA, visit What is the Therapeutic Goods Administration?

About therapeutic goods

Therapeutic goods include medicines and medical devices and have a health effect on the human body.

Consumers use them in their daily lives when they:

- apply a bandage
- take medicine to relieve a headache
- take vitamin tablets or apply sunscreen
- take a prescription medicine
- accept a vaccine, blood product or surgical implant.

For more information, see What are therapeutic goods?

These products are regulated by the TGA. Other types of products, such as cosmetics, also become subject to regulation as a therapeutic good if they are represented for therapeutic use.

Claims such as '*removes toxins*', '*fades age spots*', '*relieves pain*', '*aids sugar metabolism*', '*reduces inflammation in the body*' are all **therapeutic use claims**.

If these kinds of claims are made in an advertisement, then the advertised product will likely be considered a therapeutic good and therefore regulated under therapeutic goods legislation.

Therapeutic goods and consumer protection

Therapeutic goods are not ordinary items of commerce. They are intended to have an effect on the body, and there may be risks involved with their use.

The therapeutic goods legislation ensures advertisements for therapeutic goods do not encourage inappropriate or irresponsible use of the goods.

About social media advertising

Not all information about therapeutic goods is advertising and the definition of 'advertise' in relation to therapeutic goods is broad.

Any statement, pictorial representation or design that is intended, whether directly or indirectly, to promote the use or supply of the products is an advertisement.

A social media post that promotes the use or supply of therapeutic goods is an advertisement.

Whether an advertisement for therapeutic goods appears on social media or in any other media, **the advertisement must comply with therapeutic goods legislation**.

Find out more about the types of activities that are considered advertising at Activities that represent advertising.

Basic advertising rules

Before you advertise therapeutic goods, it is your responsibility to understand the legislative requirements.

Advertisements are required to comply with the advertising requirements set out in the *Therapeutic Goods Act 1989* and the Therapeutic Goods Advertising Code.

Advertisers may also find it helpful to:

- consult with their industry body or representative on the Therapeutic Goods Advertising Consultative Committee
- seek advice from a regulatory affairs consultant
- obtain independent legal advice.

The Code sets the requirements advertisers must meet to ensure the marketing and advertising of therapeutic goods:

- is conducted in a manner that promotes the quality use of the product

- is socially responsible
- does not mislead or deceive the consumer.

Some of the basic advertising rules require an advertisement to:

- Be accurate, balanced and substantiated (refer Part 3 of the Code).
- Only make claims that are consistent with the advertised good's indication or intended purpose as it is recorded on the Australian Register of Therapeutic Goods (the ARTG) or for exempt goods not on the ARTG consistent with documentation provided with the good.
- Contain certain mandatory warning statements, which vary depending on the type of therapeutic good being advertised (refer Part 4 of the Code).
- Only use testimonials that comply with the Code - testimonials must comply with all applicable aspects of the Code, not just the requirements set out in Part 6, section 24 of the Code.
- Not claim that a product can diagnose, treat or cure a serious condition without prior permission or approval from the TGA.

Some therapeutic goods, including prescription and certain pharmacist-only medicines are prohibited from being advertised directly to the public. These products are higher risk and their safe and appropriate use requires health professional oversight to ensure the benefits outweigh the harms for each individual.

Advertising the price of these medicines is permitted when the conditions in Part 9 of the Code are followed.

The TGA has powers to direct advertisers to take down non-compliant advertising and can pursue criminal or civil penalties against advertisers who put consumers at risk. Heavy fines and penalties apply.

For more information, see our warning to advertisers and check out the Advertising Hub on the TGA website.

Business owner responsibilities

Business owners are responsible for the content of any social media page created or managed by them, including websites, social media channels, blog posts, hashtags, or discussion forums. This responsibility extends to user-generated content, such as third-party comments posted on those social media platforms that are controlled by the business.

All advertising for therapeutic goods must promote the safe and responsible use of those products and must not take advantage of consumers, including through third party comments on social media.

Compliance with the advertising requirements under therapeutic goods legislation means that social media advertisements for therapeutic goods must meet the following requirements.

- Requirements include: Advertisements must include the relevant mandatory statements, including health warnings where applicable.
    - Health warnings must be prominently displayed or communicated at the point of purchase, including purchases via social media.
    - In social media, the mandatory statements and health warnings must be visible at all times and not within collapsed information as that does not meet the requirement for prominently displayed or communicated.
- Advertisements must not promote a therapeutic good for a purpose other than the purpose accepted by the TGA and entered in the Australian Register of Therapeutic Goods, or for exempt goods not required to be on the ARTG, a purpose other than those in the documentation provided with the good.
- Advertisements must not contain prohibited or restricted representations without prior permission or approval from the TGA.
- Advertisements must not promote goods with therapeutic use claims if those goods are not included in the Australian Register of Therapeutic Goods (unless the goods are exempt from being on the register).
    - Making therapeutic use claims about a product in an advertisement will generally make the advertisement subject to the legal requirements for advertising therapeutic goods, even if the product may not ordinarily be considered a therapeutic good.
    - An exception applies for foods for which there is a food standard. To find out if a food standard applies, go to the 'food medicine interface' guidance tool on the TGA website.
- Advertisements must not contain testimonials or endorsements which breach the Code.
- Advertisements using endorsements and testimonials must comply with Part 6 of the Code.
- Advertisements cannot include testimonials made by a person who has received 'valuable consideration' for making the testimonial. Valuable consideration is payment of some value (such as monetary payment or free product).
- Advertising cannot contain testimonials and endorsements made by health professionals and others mentioned in Part 6 of the Code.

The TGA recommends that businesses adopt an 'acceptable use policy' on its own social media pages, warning third parties that non-compliant comments will be removed from the page.

Although it is up to the party that is responsible for the advertising to ensure compliance with the requirements, we recommend that businesses also provide corrective information if they become aware of misinformation from third parties on social media channels for which they are not responsible. Advertisers should ensure any corrective information also complies with the advertising requirements if it is used within an advertisement or is an advertisement in its own right.

Tips for social media influencers

If you are an influencer who is involved with a business selling or promoting therapeutic goods (for example, you have been paid or given a product by the company to promote their goods), you should consider the following tips.

- Any post about a therapeutic good that you make may be considered advertising. If it is, you have an obligation to comply with the advertising requirements for therapeutic goods.
- Any comments you make about your personal experience with the goods amounts to a testimonial. Testimonials are not permitted by those involved in the production, sale, supply or marketing of the goods. This includes influencers who are engaged by a therapeutic goods company to promote the goods, or anyone who receives valuable consideration (payment or goods, for example) for making a testimonial.
- Your social media posts may have an impact on your followers' beliefs, attitudes, preferences and behaviours. Your comments about therapeutic goods can influence consumers' choices. Therapeutic goods should be chosen on the basis of clinical need, not through the persuasion of influencers.
- Understand what the TGA approved purpose of the good is and do not advertise the good for a purpose other than that, even if your experience with the good is otherwise. For more information about the intended purpose of a therapeutic good, refer to the product entry on the Australian Register of Therapeutic Goods.
- Seek advice from a lawyer or regulatory affairs consultant if you are unsure about your obligations in relation to social media advertising of therapeutic goods, or submit an advertising enquiry to the TGA. For more information about advertising therapeutic goods, visit the TGA Advertising Hub.

Topics: Advertising

Page history

31 March 2022
Original publication.

Chair's brief
Marketing in Australia of Infant Formulas (MAIF) Agreement
Complaints Committee
Meeting 17
Wednesday 13 November 2024
2:30-4:30pm AEST

Members:
Adjunct Associate Professor Kellie Wilton (Chair), Independent Representative
Mr Jonathan Chew, Industry Representative
Emeritus Professor Jane Scott, Public Health Representative

Secretariat:
s47E(c), s47F, Director, Nutrition Policy
s47E(c), s47F, A/g Assistant Director, Nutrition Policy
s47E(c), s47F, Departmental Officer, Nutrition Policy
s47E(c), s47F, Departmental Officer, Nutrition Policy

Item 1 | Welcome and acknowledgement to country (2:30pm)
- Welcome members to the 17th meeting of the MAIF Complaints Committee
- Acknowledgement of country:
  'I wish to acknowledge the Ngunnawal people as traditional custodians of the land we are meeting on and recognise any other people or families with connection to the lands of the ACT and region. I wish to acknowledge and respect their continuing culture and the contribution they make to the life of this city and this region. I would also like to acknowledge and welcome other Aboriginal and Torres Strait Islander people who may be attending today's event.'
- Remind members of their confidentiality requirements. Including that discussions and decisions of the committee must remain confidential.

Item 2 | Update of Declarations of Interest register and agreement to publish (2:35pm)
- Request members declare any new interests before considering any of the complaints for this meeting.
- Remind members to email any new interests to the MAIF secretariat (to be recorded in the register and published on the Department's website).

Item 3 | Meeting 16 Minutes – 20 October 2023 (2:40pm)
Item 3a | Action Items
- Outline that the majority of the action items will be addressed or considered as part of today's agenda or have since been actioned by Secretariat and are now closed.

Item 4 | Complaints from previous meeting (2.45pm)
- Note the complaints that have been finalised since the previous meeting (Meeting 16, 20 October 2023). See agenda papers for summary table of actions.

Internal note to Chair:
- These complaints are yet to be published on the MAIF website. The reason for this is discussed further under Item 8a - Publishing of complaints on the MAIF website.

Item 5 | New complaints (2:50pm)

Item 5a | New in-scope/Not yet determined

- Members to discuss new complaints for final determination. Note that only those complaints that did not have member consensus during the offline, initial determination stage, are for discussion.
- Please see Attachment A for the collated PDF of complaints and company responses for new complaints.

Internal Note to Chair:

- Secretariat will display on screen the relevant company responses and/or the complaint to assist member discussion.

Item 5b | New complaints – Determined out of session – for noting

- Note the new complaints determined out of session by Committee.
- Note that for out-of-scope complaints, complainants have received an email from secretariat informing them their complaint is out-of-scope.
- Advise members that moving forward, Secretariat should only action out of scope complaints once the Committee have reviewed.

Internal Note to Chair:

- Previously Secretariat would complete out-of-scope complaints and members would note them as completed out of session or at a meeting.

Item 6 | MAIF guidance documents (3:15pm)

Item 6a | Clause 7 Guidance document

- Facilitate member discussion for Clause 7 Guidance Document on whether further updates are required to dot point two under sub-heading 'Inducements'.
    - *Do members agree on the proposed wording changes to 'competitions' to align with Medicines Australia?*
    - *If not, do members have any alternative suggestions or concerns?*
- Seek member agreement to approve the Clause 7 Guidance and if required with edits.

Internal Note to Chair:

- The concerns around competitions in the draft Clause 7 Guidance was raised by Jane who is of the view that competitions should not be allowed, whatever the value and suggested considering aligning the wording used around competitions in other settings such as the pharmaceutical drug setting.
- Medicines Australia under Section 2.7 notes that Competitions and quizzes may be run by member companies and are acceptable, but no prize or "gift" may be offered under any circumstances.
- Currently the Draft Clause 7 allows the prizes but should be of low value not exceeding $100 to be seen not as an inducement.
- Secretariat will raise on screen the Draft Clause 7 Guidance or relevant documents to assist member discussion.

Item 6b | Electronic media guidance document

- Facilitate member discussion about the Electronic Media Guidance document.
- Facilitate the discussion in a workshop style with the objective to extract initial reactions and facilitate discussion on the preferred approach to progress with this work.
    - Proposed approach: You may wish to test member reactions to the viability of addressing this issue by making targeted edits to the guidance, including adding in case studies and FAQ's based on the table of past examples in the papers. TGA (Attachment F) style "Tips for Influencers" may also be appropriate/useful.
- Attempt to achieve member alignment on next steps, providing direction to the Department on activities to take forward and preferred timeframes for implementation. Ideally the Committee would consider a draft out-of-session with a view to finalising the updated guidance at its February 2025 meeting.

Internal Note to Chair:

- This is a short agenda item (no more than 30 mins), this item is the first conversation on this issue and the goal is to generate member engagement and support alignment between members on how to take this forward.

10 MINUTE BREAK – 3:45pm

Item 7 | Departmental Updates – Written update (3:55pm)

- Take the written Department updates as read.
- Invite members to ask questions.
- Hand over to Secretariat who will answer questions from members (s47E(c), s47F , Director, Nutrition Policy Section).

Item 8 | Committee matters (4:00pm)

Item 8a | Publishing of complaints on MAIF website

- Hand over to s47E(c), s47F to introduce this item.
- Invite members to ask questions and provide comments.

Item 8b | Committee Membership Update

- Facilitate member discussion on the desirable skill set required for the additional independent member.
- Note that in the MAIF Review, a broader representation of stakeholder groups and expertise on the MAIF Complaints Committee was identified as having the potential to enhance its independence and effectiveness. Additional members could bring particular expertise to the committee for example, legal, marketing, and communications.
- Attempt to achieve member alignment on the key expertise required and seek member input on suitable candidates for Secretariat to approach.

Item 8c | Annual reports

- Note Secretariat's preference regarding the publishing of complaint outcomes on the Departments website and to update the structure for the upcoming Annual Report.
- Hand over to Secretariat Team who will answer questions from members.
- Seek members views on whether members agree with the proposed update.

Item 9 | Other Business (4:25pm)

- Seek member confirmation of the proposed dates for 2025, to be on the third Wednesday of every month:
    - 19 February 2025
    - 21 May 2025
    - 20 August 2025
    - 19 November 2025
- Next meeting date - 19 February 2025

<u>Internal Note to Chair:</u>

- Secretariat will publish confirmed dates to the MAIF website

Item 10 | Meeting Close (4:30pm)

- Thank members and close the meeting.

Actions Table – Meeting 17

Item	MAIF complaints Meeting/Agenda item	Action	Who	When	Status
1	**Meeting 17: 13 November 2024** Item 5a: New complaints - New in-scope or not yet determined	Secretariat to draft letters from the Chair to companies and complainants in relation to the following complaints 2324-02, 2324-07, 2324-03, 2324-04, 2324-05, 2425-07.	Secretariat	Nov 2024	Not commenced
2	**Meeting 17: 13 November 2024** Item 5a: New complaints - New in-scope or not yet determined	Secretariat to provide company response to the Committee for offline consideration and final determination - 2425-02.	Secretariat	1 Dec 2024	Not commenced
3	**Meeting 17: 13 November 2024** Item 5b: New complaints – Determined out of session – for noting	Secretariat to draft letter from the Chair to company and complainant in relation to the following complaints 2324-01, 2324-06.	Secretariat	Nov 2024	Not commenced
4	**Meeting 17: 13 November 2024** Item 5b: New complaints – Determined out of session – for noting	Secretariat to reflect complaint 2425-03 and 2425-04 as *Out of Scope – Other* in the Annual Report 2024-25.	Secretariat	Nov/Dec 2024	Not commenced
5	**Meeting 17: 13 November 2024** Item 6a | Clause 7 Guidance	Secretariat to update the wording of the Clause 7 guidance document and circulate to the Committee for endorsement.	Secretariat	Nov 2024	Not commenced
6	**Meeting 17: 13 November 2024** Item 6b | Electronic Media Guidance	Secretariat to amend the Electronic Media Guidance in line with the Committees feedback and circulate to the Committee for further input.	Secretariat	Nov/Dec 2024	Not commenced
7	**Meeting 17: 13 November 2024** Item 8a| Publishing of complaints on the MAIF website	Secretariat to consider this one forward acknowledging Committee concerns.	Secretariat	Dec 2024	Not commenced

8	**Meeting 17: 13 November 2024** Item 8b| Committee Membership Update	Members to recommend suitable candidates for the Department to consider by Thursday, 21 November 2024.	Members	Nov 2024	In progress
9	**Meeting 17: 13 November 2024** Item 8b| Committee Membership Update	Secretariat to action the onboarding process for the additional member once members have provided contact details.	Secretariat	Dec 2024/Jan 2025	Not commenced
10	**Meeting 17: 13 November 2024** Item 8c| Annual Reports	Secretariat to investigate the feasibility of this option further with the departments Web Team.	Secretariat	Nov 2024	Not commenced
11	**Meeting 17: 13 November 2024** Item 8c| Annual Reports	Secretariat to draft the Annual Report 2023-24 for members to endorse.	Secretariat	Dev 2024	Not commenced
12	**Meeting 17: 13 November 2024** Item 9a| Next meeting date	Secretariat to post 2025 meeting dates on the department's website.	Secretariat	Dec 2024	Not commenced
13	**Meeting 17: 13 November 2024** Additional business raised	Secretariat to consider further the option of holding a signatory's Forum.	Secretariat	TBA	Not commenced

Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement (MAIF Agreement) Complaints Committee

Meeting 17 – Wednesday 13 November 2024, 2:30pm – 4:30pm AEDTTrish

MINUTES

Attendees

Committee member

Adjunct Associate Professor Kellie Wilton (Chair), Independent representative - In person attendance
Emeritus Professor Jane Scott, Public Health representative – In person attendance
Mr Jonathan Chew, Infant Formula Industry representative – virtual attendance

Secretariat (Nutrition Policy Section, Department of Health and Aged Care)

s47E(c), s47E - Director - virtual attendance
s47E(c), s47F – A/g Assistant Director – virtual attendance
s47E(c), s47F - Departmental Officer – In person attendance
s47E(c), s47F - Departmental Officer – In person attendance

Minutes

Meeting Opened at 2:30pm

Item 1 | Welcome and acknowledgement to country

The Chair welcomed the Committee to meeting 17 of the MAIF Complaints Committee (hereafter the Committee) held with some Committee members attending virtually and others attending face-to-face in Canberra acknowledging the lands in which we met on. The Chair reminded Members of their confidentiality obligations.

Item 2 | Updates of Declaration of Interest Register and agreement to publish

Members were invited to declare any new interests. Adjunct Associate Professor Kellie Wilton (Chair) informed members she has accepted the role of Chief Nursing and Midwifery Officer Northen Territory, which involves overseeing some Baby Friendly Health Initiative (BFHI) Hospitals. No additional interests were declared.

Item 3a | Meeting 16 (20 October 2023) – Action Items

Members noted progress against action items. The Chair noting some items as "closed" for discussion at Item 6a and 6b.

Item 4 | Complaints from previous meeting (20 October 2023)

Members noted the complaints completed from previous meeting, 20 October 2023. Discussion ensued regarding the delay in releasing the final determination letters. MAIF Secretariat explained the delay acknowledging their shortcomings and assured all members that future processes would be timelier and more efficient. Noting further discussion on this topic to take place under Item 8a.

Item 5a | New complaints – New in-scope or not yet determined

2324-02 – Bellamy's Organic

Complaint: Alleged breach of clause 5(a) relating to company signage at the FIFA Soccer World Cup promoting infant formula in Chinese writing which translated to "the leader of infant milk powder".

Key Comments:

s47E(d), s47C

[redacted]

Decision: Breach
ACTIONS: • Secretariat to draft letter to company advising of final determination and upload breach to website. • Secretariat to draft letter to complainant advising of final determination.

2324-07 – Bellamy's Organic

Complaint: Alleged breach of clause 5(a) relating to company signage during the FIFA Soccer World Cup, promotion of their toddler milk product ad and signage promoting infant formula in Chinese writing which translated to "Australian organic infant milk powder leader".

s47E(d), s47C

[redacted]

Decision: Breach
ACTIONS: • Secretariat to draft letter to company advising of final determination and upload breach to website. • Secretariat to draft letter to complainant advising of final determination.

2324-03 – Sprout Organic

Complaint: Alleged breach of clause 5(a) relating to a social media post advertising infant formula and inviting members of the public to become shareholders in the organisation.

s47E(d), s47C

[redacted]

Decision: Breach
ACTION: • Secretariat to draft letter to company advising of final determination and upload breach to website. • Secretariat to draft letter to complainant advising of final determination.

2324-04 – Sprout Organic

Complaint: Alleged breach of clause 5(a) and 5(d) relating to an email sent to their mailing list promoting their crowdfunding campaign to expand their company internationally. The email included promotional material including infant formula products and links to media coverage.

s47E(d), s47C

Decision: Breach
ACTION: • Secretariat to draft letter to company advising of final determination and upload breach to website. • Secretariat to draft letter to complainant advising of final determination.

2324-05 – The LittleOak Company

Complaint: Alleged breach of clause 5(a), 5(c) and 5(d) relating to a free brunch event run during World Breastfeeding Week 2023. The event was marketed to mothers of babies and young children and included free food, entertainment, ready to drink toddler milk a goodie bag for mum. The full product range was showcased, including Stage 1 & 2 infant formula plus imagery of infant formula on their Instagram stories.

s47E(d), s47C

Decision: Breach
ACTION:

- Secretariat to draft letter to company advising of final determination and upload breach to website.
- Secretariat to draft letter to complainant advising of final determination.

2425-02 – s47G

s47E(d), s47C

Decision: Initial determination In-scope; company response due 1 December 2024

ACTION:

- Secretariat to provide company response to the Committee for offline consideration and final determination.

2425-07 – s47G

Complaint: Alleged breach of clause 7(a) relating to a company sales representative attending a maternity facility and related conversations with hospital staff as well as emails sent from the sales representative to hospital staff.

s47E(d), s47C

Decision: No Breach

ACTION:

- Secretariat to draft letter to company and complainant advising of final determination

Item 5b | New complaints – Determined out of session – for noting

The Committee noted the complaints determined out of session. Discussion ensued regarding complaint 2425-03 and 2425-04 to change the reasoning from *Out of Scope – Retailer* to *Out of Scope – Other,* as it is considered international activity.

ACTION:

- Secretariat to draft letter to company and complainant advising of final determination for complaint 2324-01 and 2324-06.
- Secretariat to reflect complaint 2425-03 and 2425-04 as *Out of Scope – Other* in the Annual Report 2024-25.

Item 6 | MAIF guidance documents

Item 6a | Clause 7 Guidance:

The Committee acknowledged the wording used by Medicines Australia for Competitions. Members agreed to amend the wording of the Clause 7 Guidance to align with Medicines Australia removing the provision of prizes for Competitions.

ACTION:

- Secretariat to update the wording of the Clause 7 guidance document and circulate to the Committee for endorsement.

Item 6b | Electronic Media Guidance:

- The Committee acknowledge the departments commitment to improve the Electronic Media Guidance document. Members discussed the TGA Guidance and the ATO Guidance as most relevant sources of information.
- Key Comments:
  - Aligning with the TGA and ATO Guidance on social media advertising.
  - Develop case studies to include in the guidance.
  - Include the table of themes in the guidance document

ACTION:

- Secretariat to amend the Electronic Media Guidance in line with the Committees feedback and circulate to the Committee for further input.

Item 7 | Departmental Updates

The Committee noted the Departmental update and received further clarification on the 'Live Decisions Dashboard'.

Item 8 | Committee matters
Item 8a| Publishing of complaints on the MAIF website

The Committee noted Secretariat's update on publishing of complaints from the last meeting (October 2023) on the department's website. The acknowledged s47G concerns. Members agreed despite the delay, due process should be followed and publish the complaints to the website.

ACTION:

- Secretariat to consider this one forward acknowledging Committee concerns.

Item 8b| Committee Membership Update

The Committee noted that as part of strengthening the voluntary arrangements and consistent with the MAIF Review, the MAIF Complaints Committee will be expanded to include one additional independent member. Members agreed the desired skill set required is someone with a law background.

ACTION:

- Members to recommend suitable candidates for the Department to consider by Thursday, 21 November 2024.

- Secretariat to action the onboarding process for the additional member once members have provided contact details.

Item 8c| Annual Reports

The Committee acknowledged and agreed with Secretariat's proposed updates to the Annual Report and streamlining the complaints publishing process.

ACTION:

- Secretariat to investigate the feasibility of this option further with the departments Web Team.
- Secretariat to draft the Annual Report 2023-24 for members to endorse.

Item 9 | Other Business

Item 9a| Next meeting date

The Committee acknowledged the 2025 meeting dates. Members requested a change to the February 2025 date to be amended to Thursday 27 February 2025. Members agreed on all other dates.

ACTION:

- Secretariat to post 2025 meeting dates on the department's website.

Additional business raised:

Jonathan Chew raised that Infant Nutrition Council members have requested a Signatory's Forum. Discussion ensued by members regarding optics and transparency.

ACTION:

- Secretariat to consider further the option of holding a signatory's Forum.

Item 10 | Meeting Close

Meeting concluded at 4:20pm.

s22

From: maif <maif@health.gov.au>
Sent: Wednesday, 23 October 2024 9:01 AM
To: Jonathan Chew; maif
Cc: Jane Scott; WILTON, Kellie
Subject: RE: MAIF Complaints Committee Meeting 17 - Proposed Change of Date [SEC=OFFICIAL]

Hi Jonathan and Jane

Thank you for confirming your availability.

Secretariat will proceed with actioning the date change and will be in touch soon with updated details.

Many thanks
s47E(c), s47F

MAIF Complaints Committee Secretariat Team
Nutrition Policy Section

Primary and Community Care Group | Population Health Division
Preventive Health and Food Branch
Australian Government Department of Health and Aged Care
E: MAIF@health.gov.au
MDP 570, GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: Jonathan Chew s47F @infantnutritioncouncil.com>
Sent: Tuesday, October 22, 2024 5:02 PM
To: maif <maif@health.gov.au>
Cc: Jane Scott s47F @curtin.edu.au>; WILTON, Kellie s47E(c), s47F @Health.gov.au>
Subject: Re: MAIF Complaints Committee Meeting 17 - Proposed Change of Date [SEC=OFFICIAL]

Hi s47E(c), s47F

Yes, was able to rearrange to make 13 November at 2pm.

Cheers
Jonathan

Sent from my iPhone

On 22 Oct 2024, at 14:17, maif <maif@health.gov.au> wrote:

Thanks Jonathan, much appreciated.

Many thanks
s47E(c), s47F

From: Jonathan Chew s47F @infantnutritioncouncil.com>
Sent: Tuesday, October 22, 2024 2:09 PM
To: Jane Scott s47F @curtin.edu.au>
Cc: maif <maif@health.gov.au>; WILTON, Kellie s47E(c), s47F @Health.gov.au>
Subject: Re: MAIF Complaints Committee Meeting 17 - Proposed Change of Date [SEC=OFFICIAL]

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Hi s47E(c), s47F

I'm just rearranging my schedule, I should be able to confirm in the next 24 hours.

Cheers
Jonathan

Sent from my iPhone

On 21 Oct 2024, at 20:28, Jane Scott s47F @curtin.edu.au> wrote:

I can do the 13 November, and the Monday or Tuesday if needed, s22 .

Jane Scott
PhD, MPH, Grad Dip Diet, BSc, FDAA
Emeritus Professor
Public Health Nutrition
School of Population Health

Curtin University
Tel | +s47F

Email | s47F @curtin.edu.au **Web |** http://curtin.edu.au

<image002.jpg>

<image005.png>

From: maif <maif@health.gov.au>
Sent: Monday, 21 October 2024 1:33 PM

To: Jonathan Chew s47F @infantnutritioncouncil.com>; Jane Scott s47F @curtin.edu.au>
Cc: WILTON, Kellie s47E(c), s47F @Health.gov.au>; maif <maif@health.gov.au>
Subject: MAIF Complaints Committee Meeting 17 - Proposed Change of Date [SEC=OFFICIAL]

Good afternoon Jonathan, Jane

We hope you're having a good Monday.

Kellie has advised that she is required to appear at Senate Estimates. Given the uncertainty of the timing of her appearance we are proposing to reschedule the MAIF Complaints Committee Meeting 17 from Wednesday 6 November 2024 to **Wednesday 13 November 2024 at 2-4pm** (approx. time to be confirmed).

We would be grateful if you could let Secretariat know as soon as possible whether this date and time works for you.

Thank you for your understanding and flexibility.

Many thanks
s47E(c), s47F

MAIF Complaints Committee Secretariat Team
Nutrition Policy Section

<image004.png>

Primary and Community Care Group | Population Health Division
Preventive Health and Food Branch
Australian Government Department of Health and Aged Care
E: MAIF@health.gov.au
MDP 570, GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

s22

From: maif <maif@health.gov.au>
Sent: Wednesday, 23 October 2024 3:48 PM
Cc: maif
Subject: [Update] FW: Department's submission to the ACCC's Draft Determination on the re-authorisation of the MAIF Agreement [SEC=OFFICIAL]
Attachments: Submission by Department of Health and Aged Care - 17.10.24 - PR - AA1000665 INC (updated).pdf

Good afternoon members

Please disregard the submission attached to our earlier email sent on 18 October 2024. The Department of Health and Aged Care has since submitted an updated response to ACCC's Draft Determination to remove a factual inaccuracy. The submission is available for viewing on the ACCC's website at: https://www.accc.gov.au/public-registers/authorisations-and-notifications-registers/authorisations-register/infant-nutrition-council-ltd

A PDF copy is also attached for ease of reference.

Please reach out to MAIF Secretariat team at maif@health.gov.au if you have any questions.

Kind regards,

MAIF Complaints Committee Secretariat Team
Nutrition Policy Section

Primary and Community Care Group | Population Health Division
Preventive Health and Food Branch
Australian Government Department of Health and Aged Care
E: MAIF@health.gov.au
MDP 570, GPO Box 9848, Canberra ACT 2601, Australia

From: maif <maif@health.gov.au>
Sent: Friday, 18 October 2024 10:48 AM
To: maif <maif@health.gov.au>
Subject: Department's submission to the ACCC's Draft Determination on the re-authorisation of the MAIF Agreement [SEC=OFFICIAL]

Good morning members,

As you may be aware, the Australian Competition and Consumer Commission (ACCC) is currently considering an application by the Infant Nutrition Council (INC) to re-authorise the Marketing in Australia of Infant Formulas: Manufacturers and Importers (MAIF) Agreement for a period of 5 years. On 20 September 2024, the ACCC issued a draft determination proposing to deny the application for re-authorisation.

The Department of Health and Aged Care has submitted a response to ACCC's Draft Determination . The submission is available for viewing on the ACCC's website at: https://www.accc.gov.au/public-registers/authorisations-and-notifications-registers/authorisations-register/infant-nutrition-council-ltd

A PDF copy is also attached for ease of reference.

Please reach out to MAIF Secretariat team at maif@health.gov.au if you have any questions.

Kind regards,

MAIF Complaints Committee Secretariat Team
Nutrition Policy Section

Primary and Community Care Group | Population Health Division
Preventive Health and Food Branch
Australian Government Department of Health and Aged Care
E: MAIF@health.gov.au
MDP 570, GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

s22

From: Jonathan Chew s47F @infantnutritioncouncil.com>
Sent: Thursday, 26 September 2024 11:38 AM
To: s47E(c), s47F
Cc: s47E(c), s47F ; s47F ; Admin; Preventive Health Coordination
Subject: Re: Letter to DOH from Infant Nutrition Council [SEC=OFFICIAL]

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear s47E(c) s47F

Thank you to you and the Department for your support on this matter, and for allowing us to supply the letter to IP Australia for its consideration.

Cheers
Jonathan

Jonathan Chew
Chief Executive Officer

Infant Nutrition Council

AU +61 2 6273 8164 NZ +64 9 354 3272
M s47F
E s47F @infantnutritioncouncil.com infantnutritioncouncil.com

---

From: s47E(c), s47F @Health.gov.au>
Date: Thursday, 26 September 2024 at 8:31 AM
To: Jonathan Chew s47F @infantnutritioncouncil.com>
Cc: s47E(c), s47F @Health.gov.au>, s47E(c), s47F @Health.gov.au>, s47F @infantnutritioncouncil.com>, s47G @infantnutritioncouncil.com>, Preventive Health Coordination s47E(d) @health.gov.au>
Subject: RE: Letter to DOH from Infant Nutrition Council [SEC=OFFICIAL]

Dear Jonathon
Please find attached response to corro sent to Tracey Andrews 5/9/24.

As always, available to chat if that'd be helpful

s47E(c), s47E (she/her)
Director Nutrition Policy
Preventive Health and Food Policy Branch

Population Health Division | Primary and Community Care Group
Australian Government Department of Health and Aged Care
T: 02 s47E(c), s47E | E: s47E(c), s47E @health.gov.au
PO Box 9848, Canberra ACT 2601, Australia

This email comes to you from the lands of the Gadigal people of the Eora Nation
The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s47F @infantnutritioncouncil.com>
Sent: Thursday, September 5, 2024 9:48 AM
To: ANDREWS, Tracey s47E(c), s47F @health.gov.au>
Cc: s47E(c), s47F @Health.gov.au>
Subject: Letter to DOH from Infant Nutrition Council

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Good morning,

Please see attached letter from Jonathan Chew, CEO of the Infant Nutrition Council for Ms Tracey Andrews attention.

Kind regards

s47F

INC

s47F
Executive Assistant & Office Manager
Working Days: Monday, Tuesday & Thursday

Infant Nutrition Council
AU +61 2 62738164 NZ +61 9 354 3272
M s47F
E s47F @infantnutritioncouncil.com infantnutritioncouncil.com

Australian Government

Department of Health and Aged Care

Mr Jonathan Chew
Chief Executive Officer
Infant Nutrition Council Ltd
s47G @infantnutrtioncouncil.com

Dear Mr Chew

Thank you for your letter dated 5 September 2024 drawing to the Department of Health and Aged Care's (the Department) attention s47G(1)(b) The Department is concerned that public messaging of this nature contains connotations that may mislead the public and in turn, harm breastfeeding in Australia.

Despite the World Health Organization (WHO) and others recommending exclusive breastfeeding until around 6 months, this occurs for less than 40% of Australian children. Through the National Preventive Health Strategy, the Australian Government is targeting 50% of Australian infants being exclusively breastfed until six months of age by 2025.

The Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement (MAIF Agreement) aims to contribute to the provision of safe and adequate nutrition for infants, by protecting and promoting breastfeeding while also ensuring that appropriate information is provided to those who are unable to (or to make an informed choice not to) breastfeed. The Department manages the MAIF Agreement, as part of Australia's response to the WHO's International Code of Marketing of Breast-milk Substitutes. Compliance with the MAIF Agreement is monitored through the MAIF Complaints Committee. The Department considers the Trade Mark may be inconsistent with the MAIF Agreement.

I consent to you sharing this letter with IP Australia in the context of its consideration of your opposition to registration of the proposed Trade Mark. Additionally, the Department will write to s47G(1)(b) drawing its attention to the MAIF Agreement and the important role it plays in protecting breastfeeding.

Yours sincerely

s47F

Tracey Andrews
A/g Assistant Secretary
Preventive Health and Food Policy Branch
Population Health Division

25 September 2024

s22

From: maif <maif@health.gov.au>
Sent: Tuesday, 12 November 2024 10:27 AM
To: Jonathan Chew; s47E(c), s47F ; maif
Subject: RE: Update - Parking for MAIF Complaints Committee Meeting 17 [SEC=OFFICIAL]

Hi Jonathan

s22

We can certainly accommodate your attendance online tomorrow, please refer to the meeting invite to access the meeting virtually via the Teams link.

If you have any questions or difficulty accessing the meeting please reach out on (02) s47E(c), s47F .

Many thanks
s47E(c), s47F

MAIF Complaints Committee Secretariat Team
Nutrition Policy Section

Primary and Community Care Group | Population Health Division
Preventive Health and Food Branch
Australian Government Department of Health and Aged Care
E: MAIF@health.gov.au
MDP 570, GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: Jonathan Chew s47F @infantnutritioncouncil.com>
Sent: Tuesday, 12 November 2024 8:55 AM
To: s47E(c), s47F @Health.gov.au>; maif <maif@health.gov.au>
Subject: Re: Update - Parking for MAIF Complaints Committee Meeting 17 [SEC=OFFICIAL]

Thanks, s47E(c), s47F

s22

I'll be absolutely fine to do the meeting online.

Cheers
Jonathan

From: s47E(c), s47F @Health.gov.au>
Date: Tuesday, 12 November 2024 at 8:49 AM

To: Jonathan Chew s47F @infantnutritioncouncil.com>, maif <maif@health.gov.au>
Subject: RE: Update - Parking for MAIF Complaints Committee Meeting 17 [SEC=OFFICIAL]

s22

I'm sure that we can accommodate you online s47E(c), s47F
s47E(c), s47F

From: Jonathan Chew s47F @infantnutritioncouncil.com>
Sent: Tuesday, 12 November 2024 8:46 AM
To: maif <maif@health.gov.au>; s47E(c), s47F @Health.gov.au>
Subject: Re: Update - Parking for MAIF Complaints Committee Meeting 17 [SEC=OFFICIAL]

s47E(c), s47F

I'm sorry for the late notice, s22

Would it be possible to dial in to tomorrow's meeting?

Cheers
Jonathan

From: maif <maif@health.gov.au>
Date: Thursday, 7 November 2024 at 3:16 PM
To: Jonathan Chew s47F @infantnutritioncouncil.com>
Cc: maif <maif@health.gov.au>
Subject: Update - Parking for MAIF Complaints Committee Meeting 17 [SEC=OFFICIAL]

Hi Jonathan

Please see updated parking details for the new meeting date, 13 November 2024:

- Address: Yaradhang, 23 Furzer Street, Phillip, ACT, 2606
- Parking map for the basement car park is attached
  - Carpark entrance is off Furzer Street – highlighted in yellow
  - Parking space location: Park 37 - highlighted in green
- Booking Date: 13/11/2024
- Booking Time: 12-5:30pm

You will need to provide you name and car details to security via intercom to enter the carpark. Please let me know once you have arrived and I will meet you at the basement lifts across from your parking spot and bring your photo ID to sign into the building.

Many thanks
s47E(c),
s47F

MAIF Complaints Committee Secretariat Team
Nutrition Policy Section

Primary and Community Care Group | Population Health Division
Preventive Health and Food Branch
Australian Government Department of Health and Aged Care
E: MAIF@health.gov.au
MDP 570, GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: maif <maif@health.gov.au>
Sent: Thursday, 17 October 2024 4:52 PM
To: Jonathan Chew s47F @infantnutritioncouncil.com>
Cc: maif <maif@health.gov.au>
Subject: RE: Meeting update and Request for contact - Australian Dairy Nutritionals [SEC=OFFICIAL]

Hi Jonathan

Thanks for getting back to me with your info.

Carpark details for the MAIF Complaints Committee meeting on 6 November are as follows:

- Address: Yaradhang, 23 Furzer Street, Phillip, ACT, 2606
- Parking map for the basement car park is attached
    - Carpark entrance is off Furzer Street – highlighted in yellow
    - Parking space location: Park 36 - highlighted in green
- Booking Date: 06/11/2024
- Booking Time: 11:00 to 16:00

Please let me know once you have arrived and I will meet you at the basement lifts across from your parking spot. You will need to provide you name and car details to security via intercom to enter the carpark.

Please let me know if you have any questions.

Many thanks
s47E(c), s47F

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From: Jonathan Chew s47F @infantnutritioncouncil.com>
Sent: Thursday, October 10, 2024 11:44 AM
To: maif <maif@health.gov.au>
Cc: maif <maif@health.gov.au>
Subject: Re: Meeting update and Request for contact - Australian Dairy Nutritionals [SEC=OFFICIAL]

Hi s47E(c), s47F

I drive a s47F

Cheers
Jonathan

From: maif <maif@health.gov.au>
Date: Wednesday, 9 October 2024 at 4:08 PM
To: Jonathan Chew s47F @infantnutritioncouncil.com>
Cc: maif <maif@health.gov.au>
Subject: RE: Meeting update and Request for contact - Australian Dairy Nutritionals [SEC=OFFICIAL]

Hi Jonathan

I hope you're having a good week.

To allow me to secure a car space for you on the 6 November for the MAIF Complaints Committee meeting can you please provide the following information at your earliest convenience:

- Car make and model
- Number plate details

Many thanks
s47E(c), s47F

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From: Jonathan Chew s47F @infantnutritioncouncil.com>
Sent: Wednesday, October 2, 2024 12:50 PM
To: maif <maif@health.gov.au>
Cc: maif <maif@health.gov.au>
Subject: Re: Meeting update and Request for contact - Australian Dairy Nutritionals [SEC=OFFICIAL]

Hi s47E(c), s47F

Thanks for your voicemail and your email – I've just come out of meetings in Wellington.

Thank you for accommodating my request for an afternoon start on 6 November. I will drive to Canberra that morning from Sydney. Although I note that my travel is included in the committee budget, I will respectfully decline the offer and INC will cover my travel costs for this meeting (and any future in person meetings). I will gratefully accept a parking spot, thank you.

As I'm out of the office this week, I'll ask my office manager about the best point of contact for Australian Dairy Nutritionals, and come back to you on this asap.

Cheers
Jonathan

From: maif <maif@health.gov.au>
Date: Wednesday, 2 October 2024 at 3:44 PM
To: Jonathan Chew s47F @infantnutritioncouncil.com>
Cc: maif <maif@health.gov.au>
Subject: Meeting update and Request for contact - Australian Dairy Nutritionals [SEC=OFFICIAL]

Good afternoon Jonathan,

Thanks for taking my call this morning, I made a follow up call and left a message but thought I will also pop the information into an email.

I'm pleased to confirm that we can hold an afternoon meeting on the 6 November as discussed in our last catch-up, apologies for the oversight on that. We are in the process of locking in the exact time but will send out a placeholder soon.

I would also be grateful if you could get back to me regarding your travel preference. As mentioned, your travel is included in the committee budget and can be arranged by the MAIF Secretariat. I understand you had originally planned to drive to Canberra. We are happy to proceed as per your preference and can arrange parking under the building if you choose to drive.

On another note, MAIF Secretariat recently tried to contact Australian Dairy Nutritionals via the contact details for s47F @adnl.com.au, previously used. Unfortunately the correspondance was returned to sender. After some investigation I was only able to locate a general enquiries email - enquiries@adnl.com.au. Would you have updated contact details for Australian Dairy Nutritionals?

Happy to discuss.

Many thanks
s47E(c), s47F

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"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

s22

From: maif <maif@health.gov.au>
Sent: Tuesday, 15 October 2024 10:22 AM
To: WILTON, Kellie; s47F @infantnutritioncouncil.com; Jane Scott
Cc: s47E(c), s47F ; maif
Subject: For Action - DUE 30/10: MAIF Complaints Committee Meeting 17 - Initial determinations table [SEC=OFFICIAL]

Hi Kellie, Jonathan and Jane

We hope you're all having a good start to your week.

As discussed, secretariat have prepared the complaint documentation ahead of MAIF Complaints Committee Meeting 17.

Documents for your review, comments and questions:

- The initial determination table is a summary of all pending complaints to be considered as well as links to all complaints, associated links and company responses where applicable. Please provide your determination and leave any question relating to complaints within the table here: Initial determination table.docx
- If there are difficulties with the links, the overarching folder for Meeting 17 holds all the PDF documents linked within the initial determination table here: Meeting 17 - 6 November 2024

We would be grateful for your action by **COB Wednesday 30 October 2024.**

If required the MAIF Agreement and guidance documents to assist can be found in SharePoint here: Reference Materials

Next steps:

- MAIF Secretariat will collate Committee comments and prepare a draft agenda to be approved by the Committee ahead of the meeting outlining complaints where committee did not reach a consensus requiring further discussion and complaints for noting.

Please reach out if you have any questions or difficulty accessing the SharePoint documents.

Many thanks
s47E(c), s47F

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Nutrition Policy Section

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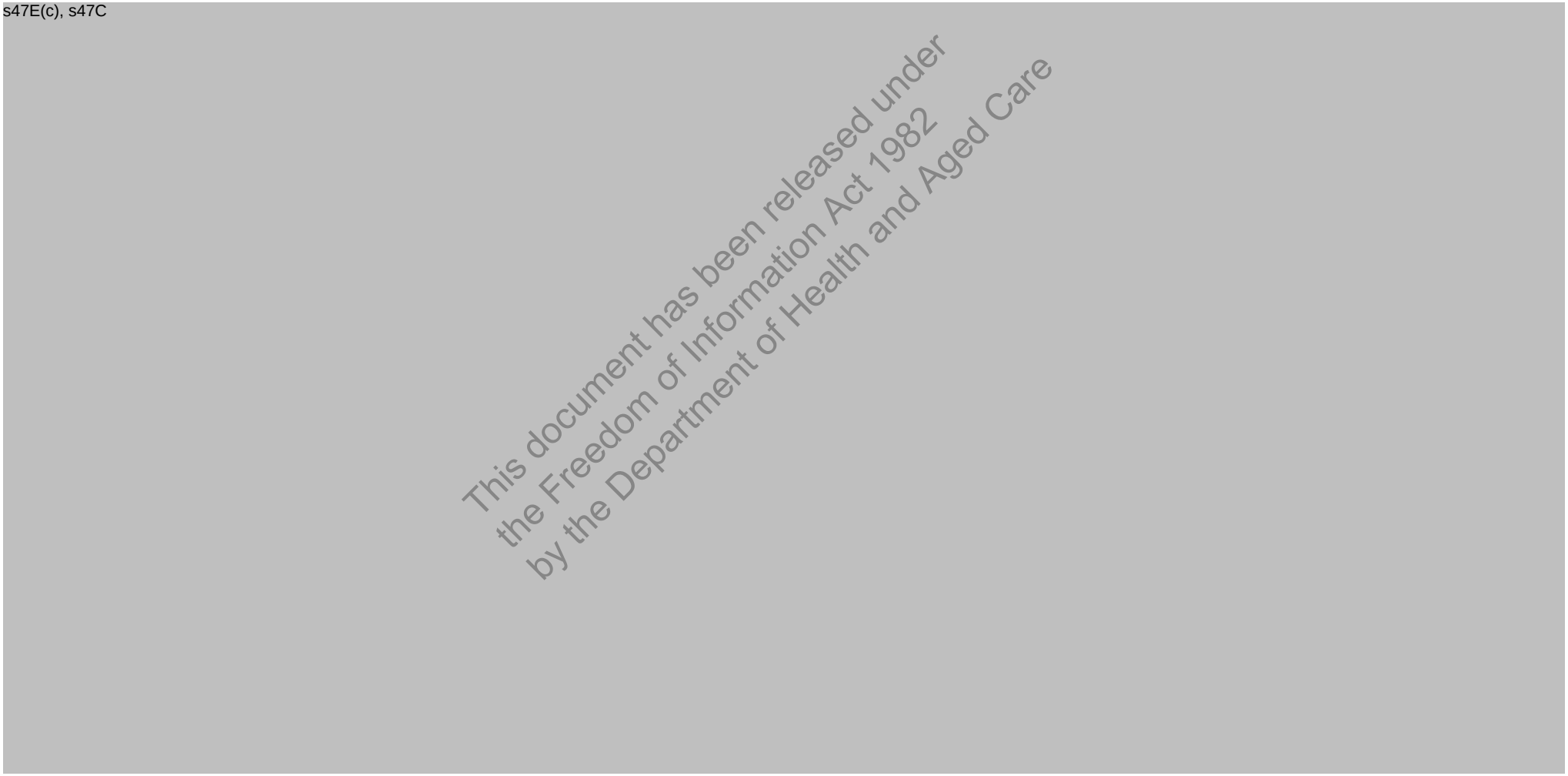
INITIAL DETERMINATIONS – MEETING 17 DATE 13 November 2024

For Committee information- It is now possible to see all ads being run by companies/pages on the Facebook platform. From 'about' section on a Facebook page, you can go to the 'page transparency' section which shows if a page is currently running ads. If they are running ads you can click through to the 'Ad library'. The Ad library shows Ad history from the start of 2023, including those that are active and whether the material is being used across other ads. You are also able to link to the specific ad.

s47E(c), s47C



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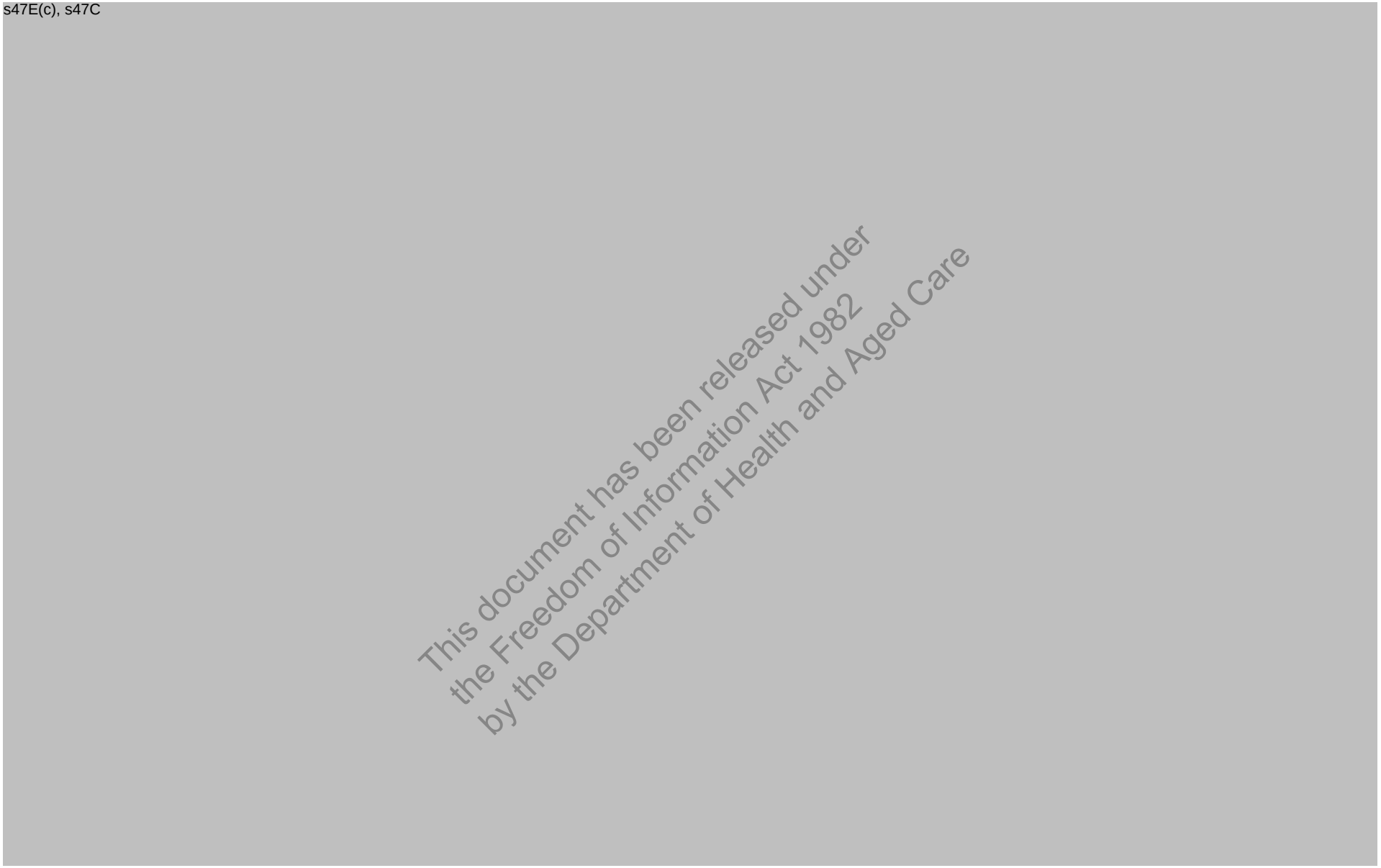
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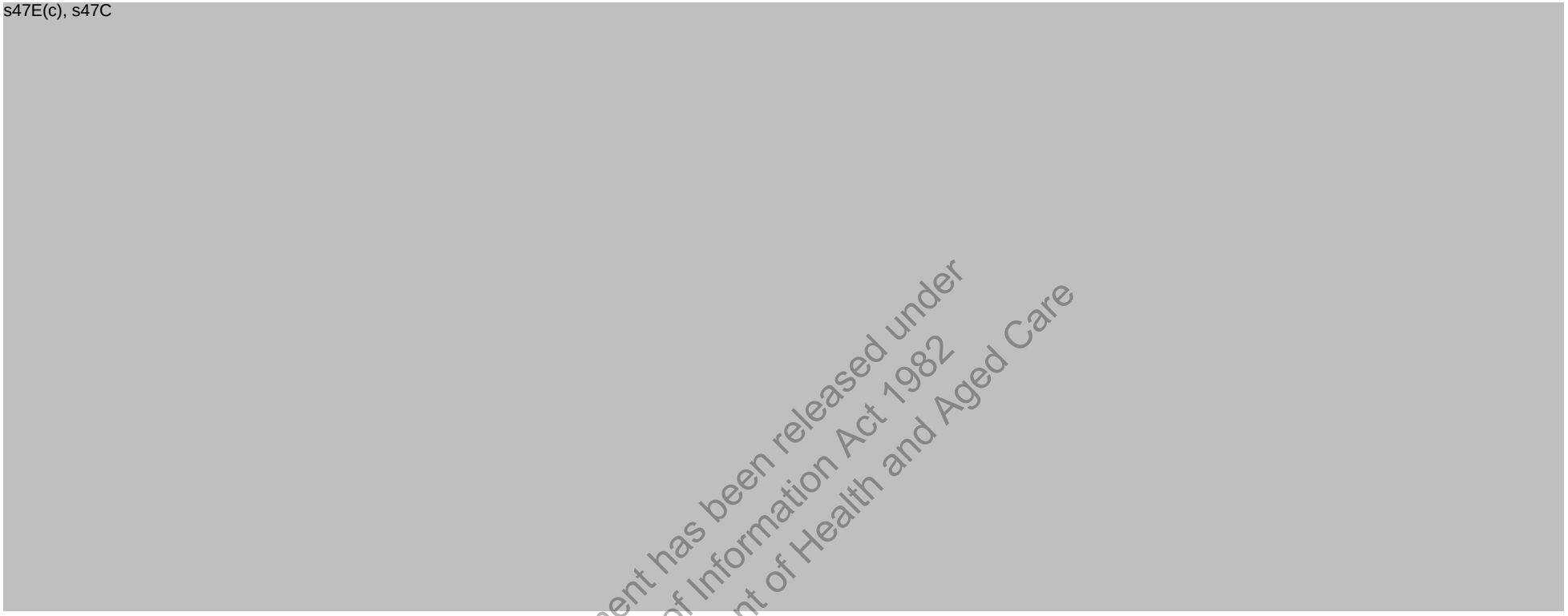

s22

From: maif <maif@health.gov.au>
Sent: Monday, 9 December 2024 3:53 PM
To: WILTON, Kellie; Jane Scott; Jonathan Chew
Cc: maif
Subject: For noting: Updated Member Guidelines - MAIF Complaints Committee [SEC=OFFICIAL]
Attachments: DRAFT - MEMBER GUIDELINES updated November 2024.docx

Hi Kellie, Jane and Jonathan

As you are aware, the MAIF Secretariat is in the process of appointing the new independent representative to the MAIF Complaints Committee, as part of that process the Member Guidelines have been updated.

For your visibility, please see attached the Member Guidelines updated in track. The changes are largely administrative, reflecting the addition of the fourth member and some further revisions throughout. Once the Member Guidelines are cleared by the First Assistant Secretary of the Population Health Division, secretariat will circulate a clean copy for your records.

As always, if you have any questions or concerns, please let me know.

Many thanks
s47E(c), s47F

MAIF Complaints Committee Secretariat Team
Nutrition Policy Section

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Australian Government
Department of Health and Aged Care

Marketing in Australia of Infant Formulas: Manufacturers and Importers (MAIF) Agreement Complaints Committee

Member Guidelines

November 2024

Table of Contents

1. Introduction

The Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement (MAIF Agreement) Complaints Committee (the Committee) was established on 5 September 2018. The Committee provides determinations on alleged breaches of the MAIF Agreement and advice on the operation of the MAIF Agreement to the relevant Australian Government Minister as required.

The Australian Government Department of Health and Aged Care (the Department) provides oversight of the handling of complaints made in relation to alleged breaches of the MAIF Agreement. A MAIF Complaints Committee Secretariat (Secretariat) located within the Department provides administrative support for the Committee.

2. Role of Committee

The role of the Committee is to receive complaints about alleged breaches of the MAIF Agreement, determine whether the complaints are in-scope or out-of-scope of the MAIF Agreement, and if in-scope, determine if a breach of the MAIF Agreement has actually occurred.

3. Terms of Reference

The Committee terms of reference are to:

- Receive complaints and determine whether they are in-scope of the MAIF Agreement.
- For in-scope complaints, investigate the complaint to determine a potential breach of the MAIF Agreement by a signatory:
    - If a complaint is considered a potential breach, correspondence will be sent to the signatory advising this and requesting the signatory provide a response should they wish to provide any information or evidence against the potential breach.
    - Following receipt of a response, the Committee will provide final determination as to whether there is a breach of the MAIF Agreement and correspondence will be provided to the signatory and the complainant advising the final decision.
    - Decisions of the Committee will be by majority.
- For out-of-scope complaints, correspondence will be provided to the signatory and the complainant advising the final decision.
- Manage and amend guidelines on the interpretation and application of the MAIF Agreement as needed; and
- Provide input into matters relating to the function of the MAIF Complaints Committee

4. Composition of the Committee

The Committee has four members comprising a Chair, and three other members.

The members include an Independent Chair with expertise in midwifery, lactation and breastfeeding. A representative of the infant formula industry. A public health representative with expertise in breastfeeding, lactation, midwifery or infant nutrition. An independent member with expertise in health law.

The members appointed to the committee are:

Adjunct Assoc Professor Kellie Wilton	Independent Member	Chair
Mr Jonathan Chew	Industry representative	Member
Adjunct Professor Jane Scott	Public health representative	Member
TBC	Independent Member	Member

5. Terms of Appointment

Each member is appointed on the basis of their individual skills, knowledge and expertise and holds their appointment at the discretion of the First Assistant Secretary, Population Health Division. The duration of Committee member appointments will be at the discretion of the delegate or until cessation of the Committee.

Members may resign from the Committee at any time by providing a letter stating their intention to resign to the First Assistant Secretary, Population Health Division (copied to the Chair and Secretariat) at least four weeks prior to the date of resignation.

The First Assistant Secretary, Population Health Division will consider appointments to vacancies as appropriate. The First Assistant Secretary, Population Health Division retains the discretion to terminate a member's appointment to the Committee at any time and for whatever reason.

6. Proxies

Where a committee member is unable to attend a meeting, proxies will **not** be allowed to attend the meeting.

7. Confidentiality

Committee members may, on occasion, be provided with confidential material. Members are not to disclose this material to anyone outside the Committee and are to treat this material with the utmost care and discretion and in accordance with terms of their confidentiality agreement.

8. Conflict of Interest

Conflict of interest is defined as any instance where a committee member, partner or close family friend has a direct financial or other interest in matters under consideration or proposed matters for consideration by the Committee. A member must disclose to the Chair any situation that may give rise to a conflict of interest or a potential conflict of interest, and seek the First Assistant Secretary, Population Health Division's/ Chair's agreement to retain the position giving rise to the conflict of interest. Where a member gains agreement to retain their position on the Committee, the member must not be involved in any related discussion or decision-making process.

A committee member is not to participate in committee business until the Confidentiality, Conflict of Interest, Privacy and Secrecy Deed Poll form has been completed (**Appendix 4**).

9. What conflicts should be declared?

Actual conflicts of interest, where an individual has an interest (whether financial or non-financial) or an affiliation that **affects or will affect** their ability to perform work under the Appointment fairly and independently. Examples include where the individual providing the declaration:

- directly benefits from the Commonwealth accepting the person's advice;
- directly receives funding from the Department under another agreement; or
- is advising on an arrangement, or assisting formulating policy relating to an industry or business, in which they have a financial interest or on which they sit on a board.

Potential conflicts of interest, where an individual has an interest (whether financial or non-financial) or an affiliation that **may affect** their ability to perform work under the Appointment fairly and independently. Examples include where the individual providing the declaration:

- is appointed as a committee member but is also an industry representative of a relevant industry;
- conducts work for other organisations who work for the Department;
- is involved in a selection process in which a relative or friend is an applicant; or
- has previously worked for, or received funding or gifts from, a company being recommended for a contract

Perceived conflicts of interest, where an individual has an interest (whether financial or non-financial) or an affiliation that **could be perceived to affect** their ability to perform work under the Appointment fairly and independently. Examples include where the individual providing the declaration:

- partakes in recreational activities which could be perceived to be at odds with the Department's agenda or objectives under the Appointment; or
- has a reasonably close friendship with a sitting member of the Parliament of Australia and they are regularly seen in public together.

A Confidentiality, Conflict of Interest, Privacy and Secrecy Deed Poll form MUST be completed by all Members on an annual basis, however, this can be updated at any time as required.

10. Official Business

A committee member will be deemed to be undertaking official committee business:

- during travel to and from and while attending meetings of the Committee, and
- while undertaking a task at the request of the Chair, including representing the Committee on other committees, sub-committees or forums approved by the Chair.

Note: Formal speeches and papers to be delivered by a member on behalf of the Committee should be cleared with the Chair and the Secretariat prior to presentation. A copy is to be provided to the Secretariat.

11. Insurance

The Department's insurance coverage for legal liabilities extends to committee members who act in an official capacity on behalf of the Department.

The Department's insurance does not extend to cover the member's private travel arrangements for example private motor vehicle or passengers.

12. Support for Committee

The work of the Committee is supported by the Secretariat located within the Nutrition Policy Section, Preventive Health and Food Policy Branch of the Department of Health and Aged Care.

Staff members of the Secretariat have knowledge of the MAIF Agreement and MAIF complaints processes, and a good knowledge of the Department's programs and organisational structure. Secretariat contact information is available at **Appendix 1**.

The Secretariat is responsible for:

- providing support to the Committee,
- providing policy advice to the Committee,
- receiving and collating complaints,
- developing, in consultation with the Chair, agendas for Committee meetings and other business involving the Department and the Committee,
- distributing of agenda, complaints and associated material,
- ensuring all members are kept informed of issues and information relevant to the work of the Committee,
- drafting and distribution of meeting minutes,
- drafting and distribution of letters on behalf of the Committee to MAIF Agreement signatories,
- arranging venues and catering for meetings,
- arranging appropriate travel and accommodation,
- verifying reimbursement of eligible expenses and
- carrying out annual conflict of interest checks.

The Department will not provide a computer or other equipment on personal issue to a member to undertake business of the Committee.

13. Operation of the Committee

The Chair is ultimately responsible to the First Assistant Secretary, Population Health Division, for the operations of the Committee. The Chair will preside at all meetings. If the Chair is unavailable for the meeting, a new meeting date will be scheduled.

The Committee normally holds four meetings each year, and members may also undertake ongoing work on specific projects on sub-committees.

A quorum for this committee will consist of all four members. Therefore, if a member is unable to attend, a new meeting will need to be scheduled. Any vacancy on the Committee will not affect its power to function.

A draft agenda will be cleared prior to each meeting by the Chair in consultation with the Secretariat. In developing the agenda, consideration will be given to the terms of reference specified by the First Assistant Secretary, Population Health Division, to the Committee.

The agenda and related papers are normally circulated to members one week prior to the meeting.

The minutes of the meeting will be prepared by the Secretariat. They will provide a concise and focused report of decisions and actions taken. Minutes will be made available to members after they have been cleared by the Chair. This will usually be undertaken within two weeks after the meeting.

14. Business between Meetings

The Chair may write and sign letters and conduct business between meetings on behalf of the Committee. The Secretariat must be provided with copies of all correspondence. Members are expected to advise the Chair and the Secretariat when they have completed agreed actions arising from previous meetings.

Any material that is considered to be of particular importance and requiring immediate action will be circulated by email.

15. Remuneration

Non Statutory Committees – Department

Not all non-statutory committee members are eligible for remuneration. The table below outlines the types of membership and eligibility for remuneration for members of non-statutory committees under the jurisdiction of the Department.

Type of Membership	Personal Income	Nature of Participation	Remunerated?
Personal	salaried	technical	no
Personal	private income lost	technical	yes
Representative	salaried	technical	no
Representative	salaried	organisational interests	no
Representative	private income lost	organisational interests	no
Consumer organisation employee	salaried	organisational interests	no
Consumer advocate	not applicable	consumer networks	yes

Below lists the current remuneration rates for the committee:

Office	Daily Fees Rate ($)
Chairperson	$1,291
Member	$971

Commonwealth and State/Territory Employees

Where a person is employed full-time by the Commonwealth (or a business owned by the Commonwealth) or in the administration of a Territory and is appointed to a part-time public office, section 7(11) of the *Remuneration Tribunal Act 1973* prevents that employee from being paid for that part-time public office, even though the Remuneration Tribunal may have set fees for that public office.

Whether a State public servant can receive payment for holding a part-time public office (for example on a Federal Government board) is a matter for the relevant State government.

16. Taxation Arrangements

Committee members who are receiving annual fees or daily fees are to notify their Tax File Number Declaration (TFD). The member must complete Tax File Declaration form (**Appendix 6)**.

Taxation instalment deductions will be calculated accordingly to the Australian Taxation Office (ATO) requirements. If the member does not provide a Tax File Number Declaration (TFD), a withholding tax will be withheld at the rate of 47% of the remuneration fee.

The Department no longer provides payment summaries. End of financial year income tax statements can be accessed through the member's MyGov account. If the member does not have a MyGov account, they should visit the following to create one:
https://www.servicesaustralia.gov.au/individuals/online-help/mygov

17. Salary Packaging

Salary packaging of committee member remuneration payments is **not** allowable for members who are remunerated on a daily fee basis.

18. Superannuation

The Department will make an employer superannuation contribution for committee members.

The committee member may choose the superannuation fund or retirement savings account to which the Department will make future superannuation guarantee contributions (10.5%).If the committee member does not make a choice, the Department's 'employer contributions' will be paid into the preferred fund of the Department. For further information on superannuation see **Appendix 7.**

19. Personal Information

The personal information a committee member provides is required to enable the Department to contact the member and to undertake any necessary financial and administrative transactions.

The general information retained by the Department may include:

- members' names,
- contact phone numbers,
- address,
- places of employment,
- curricula vitae,
- cultural background,
- correspondence to members, or
- details of submissions from the Department.

Sensitive information retained by the Department may include:

- tax file numbers,
- financial information,
- culturally sensitive issues, and
- conflict of interest details (eg previous employment with a particular entity).

Staff members have access to this information on a "needs to know" basis. Access is restricted to management and the Secretariat staff servicing the Committee. Generally, the records are retained as per the Administrative Functions Disposal Authority.

Members may contact the Freedom of Information Unit on (02) 6289 1666 or by calling the toll-free number 1800 020 103 (extension 1666) to obtain advice regarding access to their personal information.

20. Travel Arrangements

Travel Allowance Rates

Committee members travelling on official committee business are regarded as being on official government business and may receive travel allowance and reimbursement for additional expenses.

Where the committee member receives travel allowance or reimbursement of travelling expenses from any other source for the same travel, the Department will not make a payment of travel allowance or expenses to the member. Where travel on official business does not require an overnight absence, the Department will not make a payment of travel allowance.

Committee members attending an event where meals are provided will not receive the component of the travel allowance in respect of those meals. Committee members will be paid travel allowance in accordance with the Remuneration Tribunal (Official Travel) Determination 2024.The level of travel allowance is at the Tier 3 rate. Current rates of travel allowance as determined by the Remuneration Tribunal are at **Appendix 2.**

Accommodation

Accommodation may be:

- booked and paid by the Department through:
  - the accommodation reservation service provider, The Hotel Network, or
  - other accommodation providers,
- booked and paid by the committee member when making their own arrangements.

Air Travel

All committee business related flights will be booked by the Secretariat through the Department's travel management company. Committee members are not to book their own flights and seek reimbursement from the Department.

When booking travel, the Department is to comply with the Government's 'Best Fare of the Day' policy. The Best Fare of the Day is "the cheapest fare which suits official requirements". Members for this Committee are entitled to fly ECONOMY class.

Where practicable, committee members should travel on the day of the meeting or other event. Confirmation of reservation will be forwarded to members. The preferred method of air travel ticketing is an E-ticket.

Members are responsible for contacting the Secretariat if they would like their flights changed. The Secretariat will ensure the members are made aware of their revised air travel arrangements.

The Department does not belong to a frequent flyer scheme and members will not accrue frequent flyer points for air travel undertaken in conjunction with committee related business. The Department will not pay any additional costs incurred for the member's private business. The Department will not pay airline lounge membership for committee members.

Use of Private Vehicle

While air travel is the preferred means of transport, alternative means of travel may be

approved when it is considered to be in the best interests of the Department.
Members may claim motor vehicle allowance if they travel by their own vehicle to/from a meeting. Motor vehicle allowance is paid according to the Remuneration Tribunal (Official Travel) Determination 2024.

Prior to travel the Expenditure Approver has a duty of care to sight a copy of the member's driver licence, insurance and registration documentation.

The member will receive the lesser of the calculated motor vehicle allowance or the amount the Department would have to pay for the flights (where an airline service is not in operation the motor vehicle allowance is payable).

Any traffic or parking infringements sustained by the member will be the responsibility of the member.

21. Payment Arrangements

General Information

Payment of members' remuneration, travel allowance and additional expenses will be made:

- within one week following the month in which the expenditure is acquitted,
- by electronic funds transfer into a financial institution account of the member's choice.

No committee payments will be made until a completed Committee Member Onboarding form (**Appendix 5)** has been provided by the member to the Secretariat. The Department will not pay an organisation for the services of an individual on the Committee.

Remuneration Information

Remuneration Tribunal (Remuneration and Allowances for Holders of Part time Public Office) Determination 2024

Remuneration will be paid to members once the Chair has certified that members have attended a formal meeting or conducted the business of the committee. The duration of the formal meeting is to be specified.

The amount of the daily fee to be paid is calculated in accordance with Remuneration Tribunal guidelines which are summarised as follows:

- if a formal meeting is 3 hours or more – full daily fee is paid,
- if a formal meeting, or formal meeting and business of the committee on the day of a formal meeting, is two hours or more but less than three hours – an amount equal to 60% of the daily fee is paid, or
- if a formal meeting is less than two hours – an amount equal to 40% of the daily fee is paid.

The daily fee for a formal meeting includes a component to cover normal preparation time, but where the Chair considers the period of preparation time involved is so unusual as to warrant further remuneration recognition that period may be included as business of the committee.

Aggregation of hours (*sometimes referred to as Preparation Time****)***
A committee member may also be paid a daily fee in respect of aggregated periods of business of the committee subject to the following conditions:

- individual periods of business must be conducted on other than formal meeting days,
- each period must be for a minimum of one hour,
- aggregated periods must total at least five hours,
- the maximum payment in respect of any one day shall be the appropriate daily fee, and
- eligibility for each payment must be certified by the Chair.

Business between meetings
A committee member may be invited to participate in seminars, working parties or other representations between formal meetings. Such participation will be at the member's own expense unless the Chair gives approval for the member to attend in the capacity of the business of the committee.

The Secretariat must be advised of the participation of a member in such events to enable travel arrangements to be made and payments processed.

The Chair may write and sign letters and conduct business between meetings on behalf of the committee. The Secretariat should be provided with copies of all correspondence. No daily fees or travel allowance are payable for consultation between meetings.

Additional costs incurred by the member
An incidental component is included in the domestic and overseas travel allowance received by committee members. The incidentals component provides the member with assistance for costs associated with private telephone calls, extra food or drink, mini-bar, dry cleaning and newspapers.

The Department may reimburse reasonable and legitimate committee related expenses not covered by the incidental component.

Members may claim additional expenses such as taxi fares, parking fees and committee related phone calls. Reimbursement for expenses valued at $82.50 (GST incl) and above, must be accompanied by a tax invoice and all other expenditure should be evidenced by an original invoice or receipt.

Where the committee member has lost an invoice valued below $82.50, it is at the discretion of the Department's Expenditure Approver to approve the reimbursement of the unreceipted expenditure. However, in accordance with the Taxation legislation the Department must have the Tax Invoice for goods and services valued $82.50 (GST incl) and over to claim the input tax credit.

22. Media Contact

All contact with the media will require consultation with the Chair and Secretariat. Any information to be released to the media will need to be cleared through the Department's Communications Branch.

23. Forms to be Completed

Committee members will need to complete and return the following forms to the MAIF Complaints Committee Secretariat, MDP 570 GPO Box 9848, Canberra ACT 2601 or by email to maif@health.gov.au:

- Instrument of Appointment and Acceptance of Appointment Form (**Appendix 3**),
- Confidentiality, Conflict of Interest, Privacy and Secrecy Deed Poll (External Committee Members) (**Appendix 4**),
- Committee Member Onboarding Form (**Appendix 5)**,
- Tax File Number Declaration Form (**Appendix 6**), and
- Superannuation Choice Form (**Appendix 7**).

Appendix 1: List of Secretariat Staff Members

MAIF Complaints Committee Secretariat
Phone: 02 6289 7358
Inbox: maif@health.gov.au

Appendix 2: Travel Allowance Rates

Remuneration Tribunal (Official Travel) Determination 2024
www.remtribunal.gov.au

Column 1	Column 2	Column 3	Column 4
	Tier 1	**Tier 2**	**Tier 3**
Adelaide	$426	$408	$319
Brisbane	$472	$454	$342
Canberra	$461	$443	$339
Darwin	$508	$490	$381
Hobart	$450	$432	$337
Melbourne	$480	$428	$334
Perth	$480	$442	$341
Sydney	$480	$461	$359

Appendix 3: Instrument of Appointment and Acceptance of Appointment Form

See attached

Appendix 4: Confidentiality, Conflict of Interest, Privacy and Secrecy Deed Poll (External Committee Members)

See attached

Appendix 4a: Conflict of Interest Guidance Document (includes scenario examples at the end of this document)

What is a conflict of interest?

A conflict of interest can be defined as '… a conflict between the public duties and personal interests of an employee that improperly influences the employee in the performance of his or her duties.'

"Personal interests" are matters connected to an individual's personal circumstances. They may cover financial (e.g. shareholdings, small business ownership, company directorships or partnerships) and non-financial private interests (e.g. personal or family relationships or associations), as well as the private, professional or business interests of individuals or groups with whom the person has a close association (e.g. spouse or partner, relatives or close friends).

Conflicts of interest may be real or apparent. A real conflict of interest occurs when there is an actual conflict between the public duty and personal interests of an employee that improperly influences the employee in the performance of his or her duties. An apparent conflict of interest occurs where it appears that an employee's personal interests could improperly influence the performance of his or her duties, but this is not in fact the case. A real or apparent conflict of interest for contractors and consultants is any matter, circumstance, interest or activity affecting them (including their personnel) which impairs their ability to provide services to the department fairly and independently, or could be perceived or appear to do so.

The personal interests of an employee's partner or spouse, family members or close personal friends can also present a real or apparent conflict of interest for an employee, when those interests may be furthered or advantage gained through departmental policies, activities or decisions which the employee has knowledge of, or has direct and substantive influence over. Examples of situations in which the personal interests of a partner or spouse, family member or close personal friend can represent a real or apparent conflict of interest for an employee could include:

- the employee is assessing tenders from a company or organisation in which their partner or spouse, family member or close personal friend has an interest (e.g. is the business owner/partner or a company director)
- the employee is responsible for undertaking or determining regulatory activities which apply to a business or organisation in which their partner or spouse, family member or close personal friend has an interest
- two employees are in a close personal relationship or friendship, where one is able to advantage the other by influencing decisions or exercising delegations to favour them in workplace opportunities, or access to conditions, benefits or other entitlements.

The appearance of a conflict of interest is as important as any real conflict of interest. Both these situations have the potential to undermine the credibility of a project, process or decision. In situations of close personal relationships at work, real or perceived patronage or favouritism may impact on morale and productivity, as well as the credibility and professionalism of the individuals.

What needs to be disclosed?

Both section 13(7) of the PS Act and section 29 of the PGPA Act require employees to disclose 'material' personal interests relating to their employment with the department. To be 'material', the employee's personal interest must be such that a reasonable person would draw a connection between the interest and the employee's duties (i.e. there needs to be a real or reasonable possibility of conflict with the employee's duties and not simply a remote or theoretical possibility of a conflict occurring).

There is no standard list of items which must be disclosed. Employees need to consider their personal circumstances and disclose those personal interests or relationships which would reasonably be considered as 'material'. Relevant factors in determining what needs to be disclosed include:

- the department's functions and responsibilities and its particular probity concerns and
- the employee's specific role and responsibilities.

Personal interests which could be 'material' and which may need to be disclosed are not limited to financial interests and could include:

- small business ownership
- company directorships or partnerships
- shareholdings
- trusts or nominee companies
- previous employment for employees undertaking specific roles (e.g. regulatory, investigative or compliance)
- real estate investments
- gifts and benefits
- participation on boards or committees
- memberships or affiliations with associations, community groups and other organisations (either past or present)
- paid, unpaid or voluntary outside employment
- personal and family relationships or associations (either past or present)
- hostile relationships with other persons or organisations.

When can a conflict of interest occur?

A conflict of interest resulting from the interaction of an individual's personal interests, relationships or associations (either past or present) with their duties can occur in a wide range of circumstances during the course of their APS career. Without limiting the situations and circumstances where a conflict of interest may arise, the following are some of the more common situations in which employees will need to be aware of real or apparent conflicts of interest.

Participation on committees

The department has a large number of committees. Some comprise a chair and/or members appointed by the Minister. The way in which conflict of interest should be managed for committees will vary depending on:

- the nature of the committee
- the method by which the members have been selected or appointed and
- the extent to which the committee influences decision making, rather than receiving information or providing general advice.

The following model should be applied when the committee is formal, and has significant influence on decision making. This model can be modified as necessary to suit the circumstances of each particular committee, and any specific legislative requirements on the handling of conflict of interest issues (e.g. requirements contained in the *National Health and Medical Research Council Act 1982*).

If the appointment is made by the Government, within a month of being appointed, the chair of the committee must give to the Minister, and members of a committee must give to the chair, a written declaration of interests the member has that may relate to any activity of the committee. Chairs of other committees where members are appointed by the department should provide similar information to the Secretary.

In any situation that gives rise to a real or apparent conflict of interest, the member should immediately declare that conflict of interest to the chair of the relevant committee and seek the chair's agreement to retain their position.

In assessing the appropriate response if a conflict of interest has arisen, the chair of the committee should consider both the real or apparent conflict. The department should also be notified of the real or apparent conflict of interest.

If the appearance of conflict may undermine or lead to questions about the credibility of the committee of particular project, the chair should take appropriate action to avoid or minimise that impact. Ideally the person involved should step down from any involvement with that committee or particular project. This, for example, could entail not attending meetings when the committee considers the matter or not taking part in any discussion of the committee in relation to the matter.

If this is not possible because that person is the most suitable, or the only person with the required expertise, the chair should consider ways in which any actual or perceived bias can be overcome (e.g. seeking references, declaring the potential interest in documentation relating to the project). Where relevant, the public consultation process may also minimise the impact of any actual or perceived bias.

Other committees and negotiations

From time to time the department will create time-limited committees, or negotiate with external parties in order to reach agreements. For participants in such committees or negotiations, there remain personal obligations for all involved individuals to recognise and manage any conflict of interest or the appearance of such conflict.

Notwithstanding the personal obligation of each participant, departmental employees must:

- raise and document the real or apparent conflict of interest
- determine how the department should respond to any such conflicts and
- report to the Minister or Secretary as appropriate.

Managers in all forums are expected to remain alert to the possibility of a conflict of interest arising, and to raise it with the committee or other relevant body if deemed necessary. However, the actual method of dealing with a conflict of interest needs to fit the situation. The above principles apply equally to internal committees in the department where there are no or few external members. However due to the nature of the committee and the issues discussed, conflicts of interest may arise less frequently.

Regardless of the situation, it is essential that:

- any conflict of interest disclosed during a committee meeting is recorded in the minutes
- a conflict of interest disclosed to the chair outside meeting times is recorded in the minutes of the next committee meeting and
- copies of any declarations of interest are kept on file.

If minutes are not generally kept of a committee's proceedings, then the chair of the committee is responsible for documenting in a file note the declaration and subsequent decision on resolving the conflict.

Insider trading

Insider trading is the trading of securities or a wider set of financial products (as defined in s.1042A of the *Corporations Act 2001*) while in possession of information which is not generally available; and if it were, would be likely to have a material effect on the price or value of the security. Insider trading is prohibited under the *Corporations Act 2001* and has significant criminal penalties. Insider trading by a member would also be a breach of the APS Code of Conduct requirements to:

- Behave honestly and with integrity in connection with their APS employment
- Comply with all applicable Australian laws when acting in connection with their APS employment
- Not improperly use inside information to gain, or seek to gain, a benefit or an advantage for the employee or any other person and
- Behave at all times in a way that upholds the APS Values and APS Employment Principles; and the integrity and good reputation of the department and the APS.

Members should be aware that any information they access as a result of their employment with the department may potentially be considered as 'inside' or commercially sensitive information and, as such, they must not trade in shares or other financial products or induce others to do so on the basis of that information. Members must make an assessment of whether any information they have access to in the course of the duties would be considered to be inside information for this purpose, with key considerations being that:

- the information is not 'generally available' (as defined in s.1042C of the *Corporations Act 2001*) and
- if it was generally available, a reasonable person would expect it to have a 'material effect' (as defined in s.1042D of the *Corporations Act 2001*) on the price or value of financial products.

Scenario examples

Situations in which 'conflict of interest' (actual, potential or perceived) may arise in relation to external committee members

We further note the template at Appendix 4 also provides general examples of the circumstances where a member should provide a conflict of interest declaration. We consider those examples more broadly reflect the circumstances in which a conflict of interest may arise than the examples below.

Example 1

Person A is appointed to an advisory group tasked with reviewing the efficacy of various medicines that receive government subsidies. The advisory group's recommendations will be provided in a Report to the Minister and could potentially inform whether the medicines being reviewed will continue to be subsidised. Person A holds shareholding in a pharmaceutical company that manufactures a medicine being reviewed by the advisory group. Their spouse is the CEO of a pharmaceutical company which manufactures medicines being reviewed by the advisory group. Person A must disclose their shareholding because they have a financial interest in a medicine being reviewed by the advisory group. There is also a risk of a conflict (potential or perceived) in relation to their spouse's work. Therefore, Person A should also disclose information about the nature of their spouse's work.

Example 2

Person B is a member of an independent panel that reviews applications for the supply of a particular type of test kit. The panel provides its recommendations (including in relation to performance of the kit) to the relevant drug authority, who determines whether the test kit can be approved for supply based on the statutory requirements. The panel's recommendation can also be used to inform government decision on which supplier's test kit should be purchased for the national stockpile. While Person B predominately works as a medical researcher, through a consultancy arrangement, Person B occasionally collaborates with a testing company to develop and potentially commercialise test kits, that may be reviewed by the panel. Person B should disclose information about their consultancy arrangement with the testing company as there is a conflict with Person B's role on the panel. This conflict arises even though there is no testing kit currently commercialised and being considered by the panel.

Example 3

Person C is a member of a panel that assesses proposals for research funding and makes recommendations to an Agency's board as to which proposals should be awarded funding. One of the proposals, is from an organisation that Person C had recently provided consultation services in relation to an unrelated project. Person C does not know the individuals who submitted the proposal from the organisation in question and members of the panel are not aware of Person C's previous work with that organisation. There is a risk that assessment of the proposal by Person C could give rise to a reasonable apprehension of bias on the basis that Person C is directly or indirectly affiliated with the organisation seeking the grant. As a matter of caution, after becoming aware of the conflict, Person C should immediately disclose their affiliation with the organisation and not assess the relevant proposal unless the potential conflict can be otherwise appropriately managed.

Appendix 5: Committee Member Onboarding Form

See attached

Appendix 6: Tax File Number Declaration Form

See attached

Appendix 7: Superannuation Choice Form

See attached

s22

From: maif <maif@health.gov.au>
Sent: Monday, 9 December 2024 10:22 AM
To: WILTON, Kellie; Jane Scott; Jonathan Chew
Cc: maif
Subject: MAIF Complaints Committee - Complaint 2425-02 Out of Session determination and Update [SEC=OFFICIAL]
Attachments: RE: s 47G - Self report on breach [SEC=OFFICIAL]

Hi Kellie, Jonathan and Jane

Please see the below updates from Secretariat:

1. Complaint 2425-02 (s 47G) – Company response:

Secretariat have received the company response from s 47G for complaint 2425-02 s47E(d) As discussed at Meeting 17, please see the below links for the Committee Out of Session determination:

- The initial determination table includes the original complaint summary including links to the complaint form and company response letter. For ease of reference, below the table, I have also included a summary of the Meeting 17 discussions relating to this complaint - Initial determination table - Out of Session - 2425-02.docx
- If you have difficulties with the links within the initial determination table, the overarching Out of Session folder holds all the PDF documents linked within the table - Out of Session

We would be grateful for your action by **COB Monday 16 December 2024**. If a clear, consensus outcome is not possible out-of-session, we will hold this complaint over for discussion at the February 2025 MAIF Complaints Committee meeting.

2. s 47G Correspondence:

s 47E(d), s 47G

Many thanks
s47E(c), s47F

MAIF Complaints Committee Secretariat Team
Nutrition Policy Section

Primary and Community Care Group | Population Health Division
Preventive Health and Food Branch
Australian Government Department of Health and Aged Care
E: MAIF@health.gov.au
MDP 570, GPO Box 9848, Canberra ACT 2601, Australia

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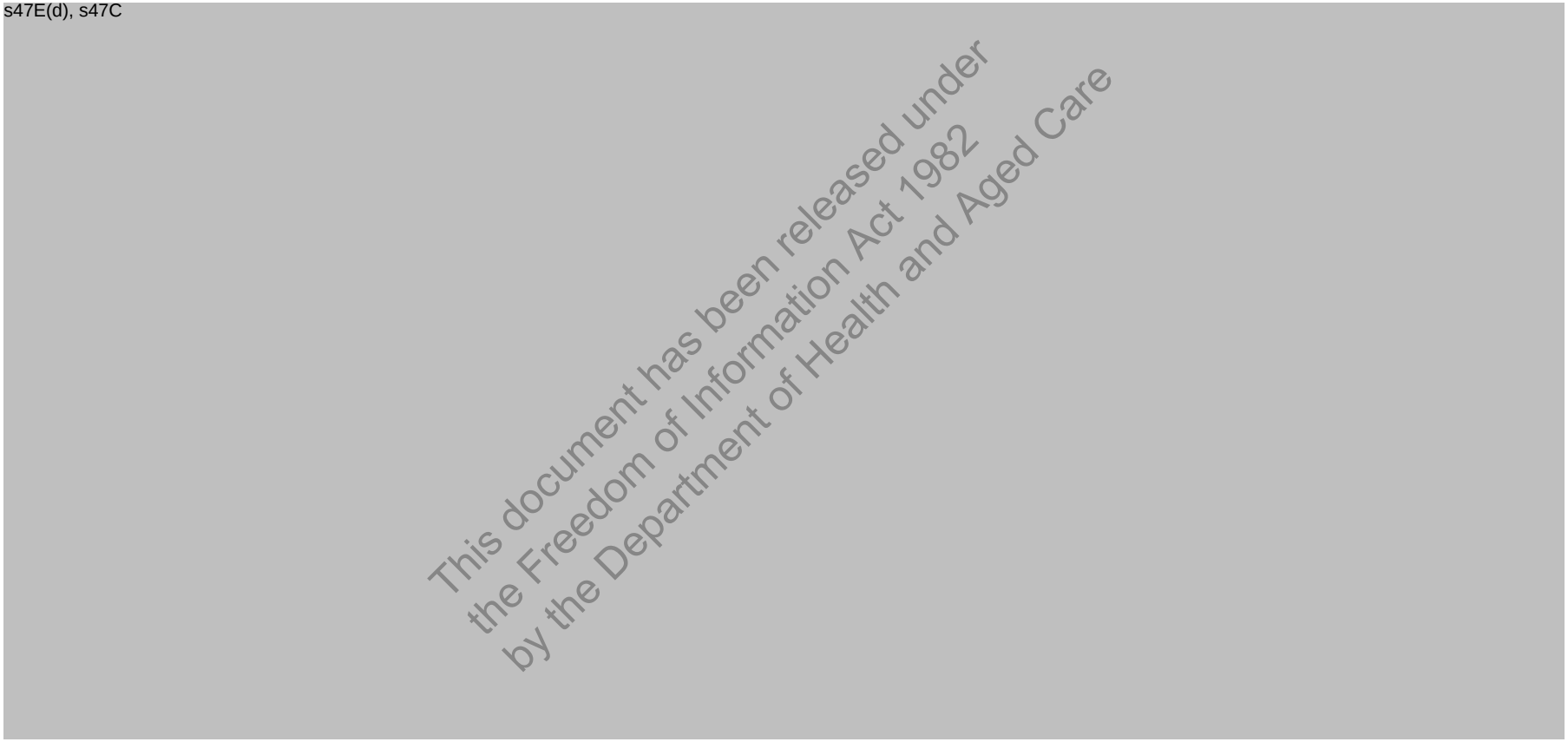
INITIAL DETERMINATIONS – MEETING 17 DATE 13 November 2024

For Committee information- It is now possible to see all ads being run by companies/pages on the Facebook platform. From 'about' section on a Facebook page, you can go to the 'page transparency' section which shows if a page is currently running ads. If they are running ads you can click through to the 'Ad library'. The Ad library shows Ad history from the start of 2023, including those that are active and whether the material is being used across other ads. You are also able to link to the specific ad.

s47E(d), s47C



Meeting 17 – Summary of discussion

s47E(d), s47C

[redacted]

s47E(d)

s22

From: maif <maif@health.gov.au>
Sent: Wednesday, 2 October 2024 2:48 PM
To: Jonathan Chew
Cc: maif
Subject: RE: Meeting update and Request for contact - Australian Dairy Nutritionals [SEC=OFFICIAL]

Hi Jonathan

Thanks for getting back to me so quickly.

Your travel preferences are noted, and a carpark will be organised for you on the 6 November 2024.

Very grateful for you following up the best contact for Australian Dairy Nutritionals, much appreciated.

Many thanks
s47E(c), s47F

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s22

From: maif <maif@health.gov.au>
Sent: Tuesday, 8 October 2024 9:29 AM
To: Jonathan Chew
Subject: RE: Meeting update and Request for contact - Australian Dairy Nutritionals [SEC=OFFICIAL]

Good morning

Thank you sharing the contacts below.

Regards,

MAIF Complaints Committee Secretariat Team
Nutrition Policy Section

Primary and Community Care Group | Population Health Division
Preventive Health and Food Policy Branch
Australian Government Department of Health and Aged Care
E: MAIF@health.gov.au
MDP 570, GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: Jonathan Chew s47F @infantnutritioncouncil.com>
Sent: Monday, October 7, 2024 7:28 PM
To: maif <maif@health.gov.au>
Cc: maif <maif@health.gov.au>
Subject: Re: Meeting update and Request for contact - Australian Dairy Nutritionals [SEC=OFFICIAL]

Hi s47E(c), s47F

Sorry for the delay. The two contacts we have for Australian Dairy Nutritionals are:

s47F

Cheers
Jonathan

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s22

From: maif <maif@health.gov.au>
Sent: Wednesday, 23 October 2024 11:40 AM
To: Jonathan Chew; maif
Subject: RE: MAIF Complaints Committee Meeting 17 - Proposed Change of Date [SEC=OFFICIAL]

Hi Jonathan,

Thanks for confirming. I will amend the parking information and confirm the new details once complete.

Thanks
s47E(c), s47F

From: Jonathan Chew s47F @infantnutritioncouncil.com>
Sent: Wednesday, October 23, 2024 11:26 AM
To: maif <maif@health.gov.au>
Subject: Re: MAIF Complaints Committee Meeting 17 - Proposed Change of Date [SEC=OFFICIAL]

Hi s47E(c), s47F

Thanks. I will drive up that morning, so would be great to have a parking spot if possible.

Cheers
Jonathan

Sent from my iPhone

> On 23 Oct 2024, at 11:21, maif <maif@health.gov.au> wrote:
>
> Hi Jonathan
>
> Thanks again for being so accommodating of the date change, its much appreciated.
>
> For the meeting on the 13 November we have landed a meeting time of 2.30-4.30pm. I wanted to confirm if you still plan to travel to Canberra by car, in which case I will organise parking, or if I can assist with booking flights for the new date?
>
> Many thanks
> s47E(c), s47F
>
> **MAIF Complaints Committee Secretariat Team**
> **Nutrition Policy Section**
>
> <image001.png>
>
> Primary and Community Care Group | Population Health Division
> Preventive Health and Food Branch
> Australian Government Department of Health and Aged Care
> E: MAIF@health.gov.au
> MDP 570, GPO Box 9848, Canberra ACT 2601, Australia

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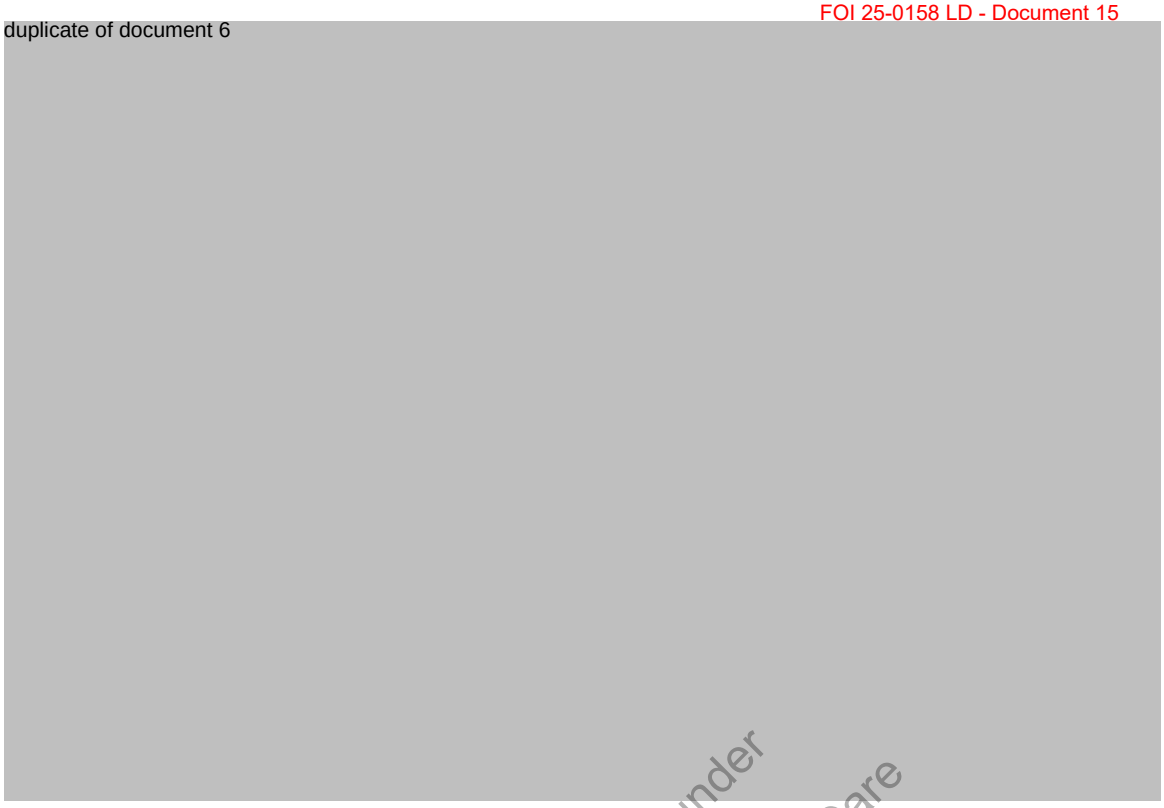

s22

From: maif <maif@health.gov.au>
Sent: Friday, 22 November 2024 1:44 PM
To: maif; WILTON, Kellie; Jane Scott; Jonathan Chew
Subject: RE: For Action DUE 21/11: Agenda Item 8c – Committee membership update [SEC=OFFICIAL]

Hi all,

Thank you for providing the contact details for potential candidates for the fourth member.

Secretariat will in touch with further updates as soon as possible.

Many thanks
s47E(c), s47F

MAIF Complaints Committee Secretariat Team
Nutrition Policy Section

Primary and Community Care Group | Population Health Division
Preventive Health and Food Branch
Australian Government Department of Health and Aged Care
E: MAIF@health.gov.au
MDP 570, GPO Box 9848, Canberra ACT 2601, Australia

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From: maif <maif@health.gov.au>
Sent: Wednesday, 20 November 2024 10:58 AM
To: WILTON, Kellie s47E(c), s47F @Health.gov.au>; Jane Scott s47F @curtin.edu.au>; Jonathan Chew s47F @infantnutritioncouncil.com>
Cc: maif <maif@health.gov.au>
Subject: RE: For Action DUE 21/11: Agenda Item 8c – Committee membership update [SEC=OFFICIAL]

Hi Members

This is a courtesy reminder to please forward any suitable candidate suggestions and their contact details by COB tomorrow, Thursday 21 Nove 2024.

Please reach out if you wish to discuss this further.

Many thanks
s47E(c), s47F

MAIF Complaints Committee Secretariat Team
Nutrition Policy Section

Primary and Community Care Group | Population Health Division
Preventive Health and Food Branch
Australian Government Department of Health and Aged Care
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MDP 570, GPO Box 9848, Canberra ACT 2601, Australia

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From: maif <maif@health.gov.au>
Sent: Thursday, 14 November 2024 12:22 PM
To: WILTON, Kellie s47E(c), s47F @Health.gov.au>; Jane Scott s47F @curtin.edu.au>; Jonathan Chew s47F @infantnutritioncouncil.com>
Cc: maif <maif@health.gov.au>
Subject: For Action DUE 21/11: Agenda Item 8c – Committee membership update [SEC=OFFICIAL]

Hi Kellie, Jane and Jonathan

We wanted to thank you all for your time yesterday to support the MAIF Complaints Committee Meeting 17.

As part of *Agenda Item 8c – Committee membership update* to include one additional member, Secretariat would like to prioritise this action to ensure a new member is onboarded by the next meeting in February 2025.

We would be grateful if you could please put forward the contact details of all the suitable candidates for Secretariat to approach and gauge their interest by **COB Thursday 21 Nov 2024**.

Please reach out if you wish to discuss this further.

Many thanks
s47E(c), s47F

MAIF Complaints Committee Secretariat Team
Nutrition Policy Section

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s22

From: maif <maif@health.gov.au>
Sent: Wednesday, 27 November 2024 12:11 PM
To: WILTON, Kellie; Jane Scott; Jonathan Chew
Cc: maif
Subject: MAIF Complaints Committee Meeting 17 - updates [SEC=OFFICIAL]

Hi Kellie, Jane and Jonathan

Please find below some updates from MAIF Complaints Committee – Meeting 17:

November Minutes:

- For Review - The draft minutes from Meeting 17 on 13 November 2024 are available in the MAIF SharePoint. Please feel free to include track changes and comments into the document.
- *Link:* DRAFT Meeting 17 - Minutes.docx

Clause 7 Guidance document:

- For noting – The revised clause 7 guidance document is available in the MAIF SharePoint, please note the updated wording relating to 'Competitions'. The has been amended to align with Medicines Australia and stipulates no prizes or gifts may be offered under any circumstances.
- *Link:* Clause 7 - MAIF Agreement Guidance FINAL 20.11.24.docx

We would be grateful if you could provide your input or endorsement by COB Friday 6 December 2024.

Please reach out if you have any questions or trouble accessing the link.

Many thanks
s47E(c), s47F

MAIF Complaints Committee Secretariat Team
Nutrition Policy Section

Primary and Community Care Group | Population Health Division
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Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement (MAIF Agreement) Complaints Committee

Meeting 17 – Wednesday 13 November 2024, 2:30pm – 4:30pm AEDT

MINUTES

Attendees

Committee member

Adjunct Associate Professor Kellie Wilton (Chair), Independent representative - In person attendance
Emeritus Professor Jane Scott, Public Health representative – In person attendance
Mr Jonathan Chew, Infant Formula Industry representative – virtual attendance

Secretariat (Nutrition Policy Section, Department of Health and Aged Care)

s47E(c), s47E - Director - virtual attendance
s47E(c), s47F – A/g Assistant Director – virtual attendance
s47E(c), s47F - Departmental Officer – In person attendance
s47E(c), s47F - Departmental Officer – In person attendance

Minutes

Meeting Opened at 2:30pm

Item 1 | Welcome and acknowledgement to country

The Chair welcomed the Committee to meeting 17 of the MAIF Complaints Committee (hereafter the Committee) held with some Committee members attending virtually and others attending face-to-face in Canberra. The traditional lands upon which the meeting is held was acknowledged. The Chair reminded Members of their confidentiality obligations.

Item 2 | Updates of Declaration of Interest Register and agreement to publish

Members were invited to declare any new interests. Adjunct Associate Professor Kellie Wilton (Chair) informed members she has accepted the role of Chief Nursing and Midwifery Officer in the Northen Territory, which involves overseeing some Baby Friendly Health Initiative (BFHI) Hospitals. No additional interests were declared.

Item 3a | Meeting 16 (20 October 2023) – Action Items

Members noted progress against action items. The Chair noting some items as “closed” for discussion at Item 6a and 6b.

Item 4 | Complaints from previous meeting (20 October 2023)

Members noted the complaints completed from previous meeting, 20 October 2023. Discussion ensued regarding the delay in releasing the final determination letters. MAIF Secretariat explained the delay acknowledging their shortcomings and assured all members that future processes would be improved. Noting further discussion on this topic to take place under Item 8a - Publishing of complaints on the MAIF website.

Item 5a | New complaints – New in-scope or not yet determined

2324-02 – Bellamy’s Organic

Complaint: Alleged breach of clause 5(a) relating to company signage at the FIFA Soccer World Cup promoting infant formula in Chinese writing which translated in English to "the leader of infant milk powder".

s47C, s47E(d)

[redacted]

Decision: Breach
ACTIONS: • Secretariat to draft letter to company advising of final determination and upload breach to website. • Secretariat to draft letter to complainant advising of final determination.

2324-07 – Bellamy's Organic

Complaint: Alleged breach of clause 5(a) relating to incidents (1) Company signage during the FIFA Soccer World Cup, (2) Promotion of their toddler milk product ad and (3) Signage promoting infant formula in Chinese writing which translated to "Australian organic infant milk powder leader".

s47C, s47E(d)

[redacted]

Decision: Breach
ACTIONS: • Secretariat to draft letter to company advising of final determination and upload breach to website. • Secretariat to draft letter to complainant advising of final determination.

2324-03 – Sprout Organic

Complaint: Alleged breach of clause 5(a) relating to a social media post advertising infant formula and inviting members of the public to become shareholders in the organisation.

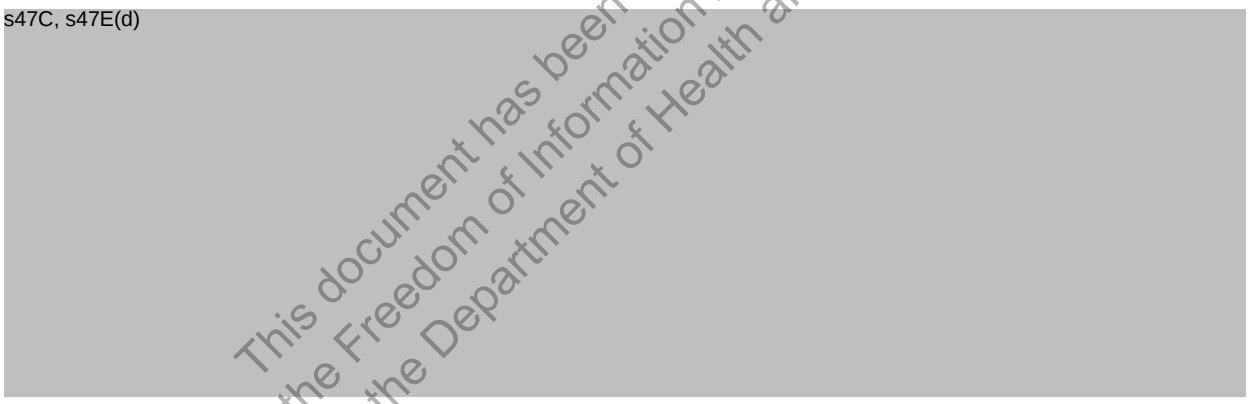
s47C, s47E(d)

Decision: Breach
ACTION: • Secretariat to draft letter to company advising of final determination and upload breach to website. • Secretariat to draft letter to complainant advising of final determination.

2324-04 – Sprout Organic

Complaint: Alleged breach of clause 5(a) and 5(d) relating to an email sent to their mailing list promoting their crowdfunding campaign to expand their company internationally. The email included promotional material including infant formula products and links to media coverage.

s47C, s47E(d)



Decision: Breach
ACTION: • Secretariat to draft letter to company advising of final determination and upload breach to website. • Secretariat to draft letter to complainant advising of final determination.

2324-05 – The LittleOak Company

Complaint: Alleged breach of clause 5(a), 5(c) and 5(d) relating to a free brunch event run during World Breastfeeding Week 2023. The event was marketed to mothers of babies and young children and included free food, entertainment, ready to drink toddler milk a goodie bag for mum. The full product range was showcased, including Stage 1 & 2 infant formula plus imagery of infant formula on their Instagram stories.

Key Comments:

s47C, s47E(d)

Decision: Breach
ACTION: • Secretariat to draft letter to company advising of final determination and upload breach to website. • Secretariat to draft letter to complainant advising of final determination.

2425-02 – s47G(1)(a)

s 47E(d), s 47G

s47G(1)(a)

Complaint: Alleged breach of clause 7(a) relating to a company sales representative attending a maternity facility and related conversations with hospital staff as well as emails sent from the sales representative to hospital staff.

s47C, s47E(d)

s47C, s47E(d)

Decision: No Breach
ACTION: • Secretariat to draft letter to company and complainant advising of final determination

Item 5b | New complaints – Determined out of session – for noting

The Committee noted the complaints determined out of session. Discussion ensued regarding complaint 2425-03 and 2425-04, s47E(d)

ACTION:
• Secretariat to draft letter to company and complainant advising of final determination for complaint 2324-01 and 2324-06. • Secretariat to reflect complaint 2425-03 and 2425-04 as *Out of Scope – Other* in the Annual Report 2024-25.

Item 6 | MAIF guidance documents

Item 6a | Clause 7 Guidance:

The Committee acknowledged the wording used by Medicines Australia for Competitions. Members agreed to amend the wording of the Clause 7 Guidance 'Competitions', that no prizes or gifts may be offered under any circumstances, subject to consultation with the MAIF signatories.

ACTION:
• Secretariat to update the proposed wording of the Clause 7 guidance document for publishing and circulate to the Committee for noting, and to consult with MAIF signatories before finalising the document.

Item 6b | Electronic Media Guidance:

- The Committee acknowledge the Department's commitment to improve the Electronic Media Guidance document. Members discussed the Therapeutic Goods Administration Guidance and the Australian Taxation Office Guidance as most relevant sources of information.
- Key Comments:
    - Align with the TGA and ATO Guidance on social media advertising and include influencers.
    - Consider the TGA Guidance information on third-party comments, noting the responsibility of signatories to moderate these comments. It was also noted that there needs to be reasonable timeframes for removal of third-party comments.
    - Consider the "breast is best" statement and social media posts, noting signatories have business owner responsibilities to use the mandatory statement when entering their website.

- Australian Health Practitioner Regulation Agency (AHPRA) was also noted as having some advertising guidance in social media e.g. cosmetic surgery.
- Case studies to include in the guidance would be helpful.
- Include the table of social media themes noted in the agenda papers in the guidance document.

ACTION:

- Secretariat to amend the Electronic Media Guidance in line with the Committee's feedback and circulate to the Committee for further input.

Item 7 | Departmental Updates

The Committee noted the Departmental update. Further clarification on the 'Live Decisions Dashboard' was provided, noting the decision dashboard will be on the MAIF website and will be updated by the MAIF Secretariat at various key stages of the complaint processes, such as when a company responses is received.

Item 8 | Committee matters
Item 8a| Publishing of complaints on the MAIF website

The Committee noted the delays in publishing of complaints from the last meeting (October 2023) on the Department's website and acknowledged s47G(1)(a) concerns. Members were of the view that despite the delays, due process should be followed, and all complaints should be published on the website.

ACTION:

- Secretariat to consider this feedback and update the Committee on the outcome.

Item 8b| Committee Membership Update

The Committee noted that as part of strengthening the voluntary arrangements and consistent with the MAIF Review, the MAIF Complaints Committee will be expanded to include one additional independent member by the next committee member in February 2025. Members agreed the desired skill set required is someone with a legal background.

ACTION:

- Members to recommend suitable candidates to the Secretariat out of session to ensure a new member is onboarded by the next Committee meeting (Feb 2025).

Item 8c| Annual Reports

The Committee acknowledged and agreed with Secretariat's proposed updates to the Annual Report and streamlining the complaints publishing process.

ACTION:

- Secretariat to proceed with MAIF website complaint updates and to draft the Annual Report 2023-24 for members to endorse.

Item 9 | Other Business
Item 9a| Next meeting date

The Committee acknowledged the 2025 meeting dates:

- 19 February 2025
- 21 May 2025
- 20 August 2025
- 19 November 2025

Members requested the February 2025 date be amended to Thursday 27 February 2025. Members agreed on all other dates.

ACTION:

- Secretariat to publish 2025 meeting dates on the Department's website.

Additional business raised:

Jonathan Chew raised that Infant Nutrition Council members have requested a Signatories Forum for educational purposes. Discussion ensued by members regarding requirements for a forum and optics e.g. a separate forum for public health stakeholders.

ACTION:

- Secretariat to consider further the option of holding a Signatories Forum and report back to the Committee.

Item 10 | Meeting Close

Meeting concluded at 4:20pm.

MAIF Complaints Committee's interpretation of the MAIF Agreement related to Health Care Professionals (Clause 7)

Overall Principles:

The purpose of this guidance is to support the interpretation of the Marketing in Australia of Infant Formulas: Manufacturers and Importers (MAIF) Agreement. This guidance does not replace the responsibility of the MAIF Complaints Committee to apply the MAIF Agreement objectively, using common sense in light of providing information and education, on a case-by-case basis.

These guidelines are to be read with the aim of the MAIF Agreement in mind and as an overarching principle: *to contribute to the safe and adequate nutrition for infants, by the protection and promotion of breastfeeding and by ensuring the proper use of breast milk substitutes, when they are necessary, on the basis of adequate information and through appropriate distribution.*

General Principles to Guide All Interactions with Health Care Professionals

All interactions between infant formula manufacturers and importers and health care professionals should:

- Be transparent and capable of public and professional scrutiny;
- Be carried out by representatives who are aware of the obligations of the MAIF Agreement
- Have the primary objective of providing scientific knowledge and/or providing factual information about the product

Relevant MAIF Agreement definitions

Health care system: governmental, non-governmental or private institutions engaged, directly or indirectly, in health care for mothers, infants and pregnant women and nurseries or childcare institutions. It also includes health workers in private practice. For the purposes of this document, the health care system does not include pharmacies or other retail outlets.

Health care professional: a professional or other appropriately trained person working in a component of the health care system, including pharmacists and voluntary workers.

Samples: Single or small quantities of infant formula provided without cost (WHO Code Article 3).

Information to health care professionals

1. To fulfill the aim of the MAIF Agreement, Clause 7b states that manufacturers and importers should provide information to health care professionals about their products. It is important that health care professionals have access to education on scientific and factual information about infant formulas and manufacturers and importers may play an important part in providing this information and education. Representatives of infant formula manufacturers and importers may request to visit health care professionals with the intent to educate them. It is up to health care professionals to decide whether they wish to see representatives of formula manufacturers.

2. Scientific information about infant formulas provided to health care professionals by manufacturers and importers should reflect the totality of the evidence, meaning that scientific information should reflect the current scientific knowledge comprehensively, not simply selective parts that can be used in a misleading way.

3. Scientific information should be supported by references to the scientific literature and the cited publication/s should be relevant and have been published in a peer reviewed journal. If this isn't possible, the manufacturer/importer, if requested, should be able to provide the MAIF Complaints Committee with supporting evidence and the rationale for supporting the scientific claims with that evidence.

4. The language used in scientific claims should reflect the quality and strength of the supporting reference(s)/ evidence and have regard to the GRADE framework, while noting limitations on randomisation in nutrition studies involving methods of infant feeding.

5. It is not considered a scientific or factual to claim that a product resembles, or is similar to, or is close to breast milk unless the specific nutrient that is similar to that found in breast milk is stated, and evidence is provided that satisfies the MAIF Complaints Committee that this specific claim is valid. Where these terms are used without a specific claim, the manufacturer may be considered to be implying equivalence with breast milk.

6. Information should not imply or create a belief that the infant formula product is equivalent or superior to breastfeeding.

7. The following should, where possible and relevant, be included in informational pieces when comparing breast milk with infant formula or ingredients of infant formula :
   a. the units of measurement
   b. the specific type of breast milk sample which is being compared
   c. the average or mean values and the standard deviation
   d. The references for the source of data should be provided.

Pictures on informational material or education material for health professionals

8. Information materials for health care professionals should not contain images, music or other devices that are likely to be attractive to young children, and therefore might lead to health care professionals putting them on display or giving them to children and caregivers. Examples might include toys or children's books..

9. Real infants depicted in a normal context do not necessarily idealise the use of infant formulas and may legitimately draw a health care professional's attention to information about an infant formula. However:
    - infants (with or without bottles) in fantasy or non-age-appropriate situations (e.g. stars, heavens, clouds, sitting up in school) should not be depicted because they may suggest formula-fed babies are in some way 'ahead of' or 'advanced' compared to breastfed babies;
    - infants with slogans over or adjacent to the pictures should not be used in such a way as to imply that the product is better than breast milk or idealise the use of infant formula; and
    - a picture of an apparently newly born baby should not be used to draw attention to information about infant formula. Breast milk is the best milk for babies up to 12 months old, but it is particularly valuable in the first few weeks of life when the baby is most vulnerable. Infant models for such pictures should be no younger than three months. Pictures of younger infants may be acceptable to draw attention to specialised products formulated for pre-term or low-birth weight babies for use under medical supervision.
    - A picture of a woman breastfeeding should not be used to draw attention to information about infant formula because it:
        - o May create an impression that the product is equivalent to breastfeeding;
        - o Appropriates the image of breastfeeding for the purpose of promoting a product; and
        - o May be considered a misleading way of gaining attention

    However, a picture of a woman breastfeeding may be used in the context of providing scientific and factual information about the benefits of breast milk and/or breastfeeding.

10. Cartoons and pictures of animals and toys do not necessarily idealise the use of infant formulas and therefore may be acceptable.

Inducements

- Low value items for professional use such as pens and papers (with the company name or logo only) may be handed out at a conference or provided to health

care professionals. Anything else intended or likely to be taken home may be considered an inducement and should not be left in a hospital ward or other health care facility.

- Competitions, included in information material for health professionals, which are clearly for the purpose of emphasising scientific and factual information only, may be acceptable but no prizes or gifts may be offered under any circumstances. Such competitions should not be an inducement to promote infant formulas.
- The provision of basic refreshments at informational/ educational events is acceptable provided it is in association with a presentation that coincides with a mealtime and is not of a lavish nature.
- A professional diary that contains scientific and factual information about infant formula and conforms with the requirements of the MAIF Agreement, is not considered an inducement.

Distribution and provision of samples

11. Child care centres are not a setting in which professional evaluation of infant formula occurs, there is therefore no valid reason for manufacturers to give samples of infant formula to child care or day care centres.

Sponsorship

12. Infant formula manufacturers and importers sponsoring healthcare professional conferences, seminars or publications or displaying infant formula products or information at healthcare professional events is not a breach of the MAIF Agreement. It is up to the organisers to decide whether they wish to accept sponsorships or product displays.

However:

- any sponsorship of meetings, seminars or conferences should be declared. There should be no conditions which relate to the marketing of the sponsor's product or to restrictions on promotion of breastfeeding.
- the sponsor can recommend speakers based on relevant scientific expertise and may provide them with a brief. However, the speaker has sole editorial control over the content of their presentations. Sponsorship should not be conditional on the event organiser's acceptance of the recommended speaker and the event organiser/s maintain responsibility for final approval of speaker and topic.
- any donated conference materials may bear a company's logo but should not refer directly to an infant formula product.

From: Jonathan Chew
To: maif; s47E(c), s47F
Subject: Re: For Action - DUE 30/10: MAIF Complaints Committee Meeting 17 - Initial determinations table [SEC=OFFICIAL]
Date: Wednesday, 30 October 2024 10:54:43 AM
Attachments: image001.png
image002.png
image003.png

Hi s47E(c), s47F
Thanks, that worked and I've now completed the initial determination table.
Cheers
Jonathan

From: maif <maif@health.gov.au>
Date: Tuesday, 29 October 2024 at 4:34 PM
To: Jonathan Chew s47F @infantnutritioncouncil.com>, maif <maif@health.gov.au>, s47E(c), s47F @Health.gov.au>, s47E(c), s47F @Health.gov.au>
Subject: RE: For Action - DUE 30/10: MAIF Complaints Committee Meeting 17 - Initial determinations table [SEC=OFFICIAL]

Hi Jonathan
Thanks for reaching out and apologies for the delay, we had a section planning day today and were away from our desks.
I have updated the link here Meeting 17 - 13 November 2024.
Please let me know if you have any further difficulties.
Many thanks
s47E(c), s47F

From: Jonathan Chew s47F @infantnutritioncouncil.com>
Sent: Tuesday, 29 October 2024 9:53 AM
To: maif <maif@health.gov.au>; s47E(c), s47F @Health.gov.au>; s47E(c), s47F @Health.gov.au>
Subject: Re: For Action - DUE 30/10: MAIF Complaints Committee Meeting 17 - Initial determinations table [SEC=OFFICIAL]

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Hi s47E(c), s47F
When you first sent this email, I checked the links and they all worked.
This morning, I went in to complete the work, and now I cannot access anything other than the determination table. All the links in the table, as well as thew overarching folder, are not working for me.
Grateful advice.
Cheers
Jonathan

duplicate of document 10

duplicate of document 10

s22

From: Jonathan Chew
Sent: Wednesday, 20 November 2024 2:38 PM
To: maif
Subject: Re: For Action DUE 21/11: Agenda Item 8c – Committee membership update [SEC=OFFICIAL]
Attachments: s47F CV - November 2024.pdf; CV s47F November 2024.pdf

Hi s47E(c), s47F
Please find attached two potential candidates for the role: s47F and s47F
In the interests of full disclosure, I am a longtime friend of s47F ' husband. It's possible some might consider that a conflict – so I want to be transparent about it.
Cheers
Jonathan

From: maif <maif@health.gov.au>
Date: Wednesday, 20 November 2024 at 10:57 AM
To: WILTON, Kellie s47E(c), s47F @Health.gov.au>, Jane Scott s47F @curtin.edu.au>, Jonathan Chew s47F @infantnutritioncouncil.com>
Cc: maif <maif@health.gov.au>
Subject: RE: For Action DUE 21/11: Agenda Item 8c – Committee membership update [SEC=OFFICIAL]

Hi Members
This is a courtesy reminder to please forward any suitable candidate suggestions and their contact details by COB tomorrow, Thursday 21 Nove 2024.
Please reach out if you wish to discuss this further.
Many thanks
s47E(c), s47F
MAIF Complaints Committee Secretariat Team
Nutrition Policy Section

Primary and Community Care Group | Population Health Division
Preventive Health and Food Branch
Australian Government Department of Health and Aged Care
E: MAIF@health.gov.au
MDP 570, GPO Box 9848, Canberra ACT 2601, Australia
The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: maif <maif@health.gov.au>
Sent: Thursday, 14 November 2024 12:22 PM
To: WILTON, Kellie s47E(c), s47F @Health.gov.au>; Jane Scott s47F @curtin.edu.au>; Jonathan Chew s47F @infantnutritioncouncil.com>
Cc: maif <maif@health.gov.au>
Subject: For Action DUE 21/11: Agenda Item 8c – Committee membership update [SEC=OFFICIAL]
Hi Kellie, Jane and Jonathan
We wanted to thank you all for your time yesterday to support the MAIF Complaints Committee Meeting 17.

As part of *Agenda Item 8c – Committee membership update* to include one additional member, Secretariat would like to prioritise this action to ensure a new member is onboarded by the next meeting in February 2025. We would be grateful if you could please put forward the contact details of all the suitable candidates for Secretariat to approach and gauge their interest by **COB Thursday 21 Nov 2024**.

Please reach out if you wish to discuss this further.

Many thanks

s47E(c), s47F

MAIF Complaints Committee Secretariat Team
Nutrition Policy Section

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MDP 570, GPO Box 9848, Canberra ACT 2601, Australia

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s47F

s47F

s47F

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s47F

s47F

From: maif
To: Jonathan Chew; maif
Cc: maif; s47E(c), s47F ; WILTON, Kellie; Jane Scott
Subject: RE: MAIF Complaints Committee Meeting 17 - updates [SEC=OFFICIAL]
Date: Friday, 6 December 2024 4:28:21 PM
Attachments: image001.png
image002.png

Hi Jonathan
I wanted to acknowledge your email below.
For some background, Secretariat updated this reference as it's our understanding that the Grade Framework has replaced the NHMRC Hierarchy of Evidence. We are currently going through the process to validate this and will come back to you with a response as soon as possible.
Please reach out if you have any questions.
Many thanks

s47E(c), s47F
MAIF Complaints Committee Secretariat Team
Nutrition Policy Section

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E: MAIF@health.gov.au
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From: Jonathan Chew s47F @infantnutritioncouncil.com>
Sent: Thursday, 5 December 2024 8:09 AM
To: maif <maif@health.gov.au>
Cc: maif <maif@health.gov.au>; s47E(c), s47F @Health.gov.au>; s47E(c), s47F @Health.gov.au>; WILTON, Kellie s47E(c), s47F @Health.gov.au>; Jane Scott s47F @curtin.edu.au>
Subject: Re: MAIF Complaints Committee Meeting 17 - updates [SEC=OFFICIAL]

Dear All,
This change has been shared with INC members, and there is no concern raised about the language prohibiting competition prizes.
However, several members advised there was concern about another part of the updated guidance.
This was the issue at para 4:

4. The language used in scientific claims should reflect the quality and strength of the supporting reference(s)/ evidence and have regard to the GRADE framework, while noting limitations on randomisation in nutrition studies involving methods of infant feeding.

I am advised that this was a change to the previous iteration of the guidance, which referenced the NHMRC hierarchy instead of the GRADE framework, and that INC members requested the original language (NHMRC) be retained.

Could the Secretariat provide advice on this issue?
Cheers
Jonathan

From: maif <maif@health.gov.au>
Date: Thursday, 28 November 2024 at 11:40 AM
To: Jonathan Chew s47F @infantnutritioncouncil.com>
Cc: maif <maif@health.gov.au>, s47E(c), s47F @Health.gov.au>, s47E(c), s47F @Health.gov.au>, WILTON, Kellie s47E(c), s47F @Health.gov.au>, Jane Scott s47F @curtin.edu.au>
Subject: RE: MAIF Complaints Committee Meeting 17 - updates [SEC=OFFICIAL]

Hi Jonathan
Thanks for your email.
Secretariat is happy for you to circulate the Clause 7 guidance document to MAIF Signatories, noting this is the updated version following last consultation in 2023.
For additional context, the clause 7 guidance document on the department's website is not the updated guidance. At Meeting 16 in October 2023 the Committee updated the clause 7 guidance document taking into consideration the notes from INC members collated by s47F. The Committee endorsed the wording changes with one exception around the wording relating to competitions. As you know, at Meeting 17 the Committee discussed and agreed to align the wording around competitions with Medicines Australia. This should be the only additional change to the guidance that the MAIF signatories are yet to see.
Please let me know if you have any further questions.
Many thanks

s47E(c), s47F
MAIF Complaints Committee Secretariat Team
Nutrition Policy Section

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From: Jonathan Chew s47F @infantnutritioncouncil.com>
Sent: Thursday, 28 November 2024 9:53 AM
To: maif <maif@health.gov.au>; s47E(c), s47F @Health.gov.au>; s47E(c), s47F @Health.gov.au>
Subject: Re: MAIF Complaints Committee Meeting 17 - updates [SEC=OFFICIAL]

Hi All,
Further to this, there is now a question raised by INC members as to whether the Clause 7 guidance that was consulted on in 2023 was formally adopted. We note on the

Department's website, the old guidance notes are still online, not the one that is circulated below.
When s47E(c) s47F is back from leave, can we clarify?
Cheers
Jonathan

From: Jonathan Chew s47F @infantnutritioncouncil.com>
Date: Thursday, 28 November 2024 at 8:00 AM
To: maif <maif@health.gov.au>, s47E(c), s47F @Health.gov.au>, s47E(c), s47F @Health.gov.au>
Subject: Re: MAIF Complaints Committee Meeting 17 - updates [SEC=OFFICIAL]

Hi s47E(c), s47F & s47E(c), s47F
As you know, the current MAIF Agreement operates under a self-regulatory model – the infant formula industry in Australia voluntarily agrees to commitments rendered in the text, and the guidance notes form an interpretation of how the text operates. To my understanding, this means that any changes to the text, or to the guidance notes, are done in consultation with the MAIF signatories. In the past, this has been coordinated through the INC CEO.
Obviously there have been a number of changes of personnel, including myself, since the guidance notes were last updated; however, before text is finalised, it should be shared with MAIF signatories as part of as sound and transparent process.
Although I do not foresee any concerns with these proposed changes in the guidance notes, while the MAIF Agreement remains a self-regulatory model, we should continue to follow past procedure. I am happy to circulate the text today, and given it is a minor amendment, ask for any feedback within 7 days.
I'm happy to discuss.
Cheers
Jonathan

From: maif <maif@health.gov.au>
Date: Wednesday, 27 November 2024 at 12:10 PM
To: WILTON, Kellie s47E(c), s47F @Health.gov.au>, Jane Scott s47F @curtin.edu.au>, Jonathan Chew s47F @infantnutritioncouncil.com>
Cc: maif <maif@health.gov.au>
Subject: MAIF Complaints Committee Meeting 17 - updates [SEC=OFFICIAL]

Hi Kellie, Jane and Jonathan
Please find below some updates from MAIF Complaints Committee – Meeting 17:

November Minutes:

- For Review - The draft minutes from Meeting 17 on 13 November 2024 are available in the MAIF SharePoint. Please feel free to include track changes and comments into the document.
- *Link:* DRAFT Meeting 17 - Minutes.docx

Clause 7 Guidance document:

- For noting – The revised clause 7 guidance document is available in the MAIF

SharePoint, please note the updated wording relating to ‘Competitions’. The has been amended to align with Medicines Australia and stipulates no prizes or gifts may be offered under any circumstances.

- *Link:* Clause 7 - MAIF Agreement Guidance FINAL 20.11.24.docx

We would be grateful if you could provide your input or endorsement by COB Friday 6 December 2024.

Please reach out if you have any questions or trouble accessing the link.

Many thanks

s47E(c), s47F

MAIF Complaints Committee Secretariat Team

Nutrition Policy Section

Primary and Community Care Group | Population Health Division

Preventive Health and Food Branch

Australian Government Department of Health and Aged Care

E: MAIF@health.gov.au

MDP 570, GPO Box 9848, Canberra ACT 2601, Australia

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From: Jane Scott
To: maif
Subject: RE: For Action - DUE 30/10: MAIF Complaints Committee Meeting 17 - Initial determinations table [SEC=OFFICIAL]
Date: Monday, 4 November 2024 1:23:18 PM
Attachments: image015.png
image001.jpg
image002.png
image003.png
image004.jpg
image005.jpg
image006.jpg
image007.png

Hi s47E(c), s47F
I've finished the table including all of those that were out of Scope.
Best wishes,
Jane

Jane Scott
PhD, MPH, Grad Dip Diet, BSc, FDAA
Emeritus Professor
Public Health Nutrition
School of Population Health

Curtin University
Tel | +s47F

Email | s47F @curtin.edu.au Web | http://curtin.edu.au

PAC-COVID-ReturntoCampus-emailsignaturebanner

From: maif <maif@health.gov.au>
Sent: Monday, 4 November 2024 5:43 AM
To: Jane Scott s47F @curtin.edu.au>; maif <maif@health.gov.au>
Subject: RE: For Action - DUE 30/10: MAIF Complaints Committee Meeting 17 - Initial determinations table [SEC=OFFICIAL]

Good morning Jane
Thanks for letting me know and I'm sorry you're having trouble accessing the SharePoint page.
In the first instance I have removed and re-allocated your access to see if this fixes the issue, please try accessing the site this morning and let me know if you have any further trouble. I have provided the links below for ease:

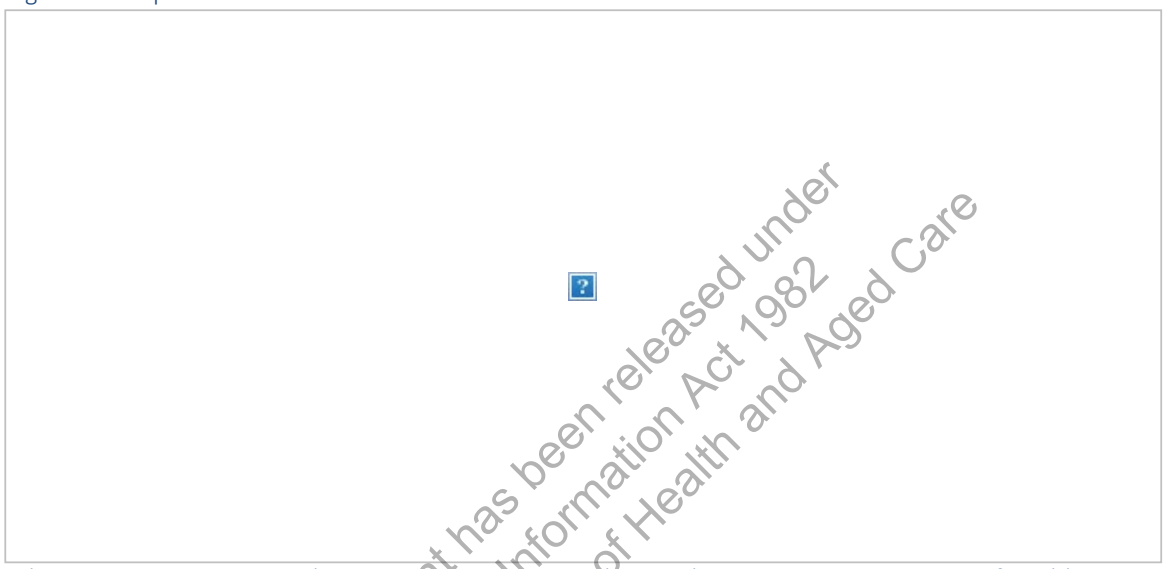
- Initial determination table.docx
- Meeting 17 - 13 November 2024

If this does not work, I will send you a copy of the initial determination table and associated complaint attachments via email to work through offline.
Many thanks

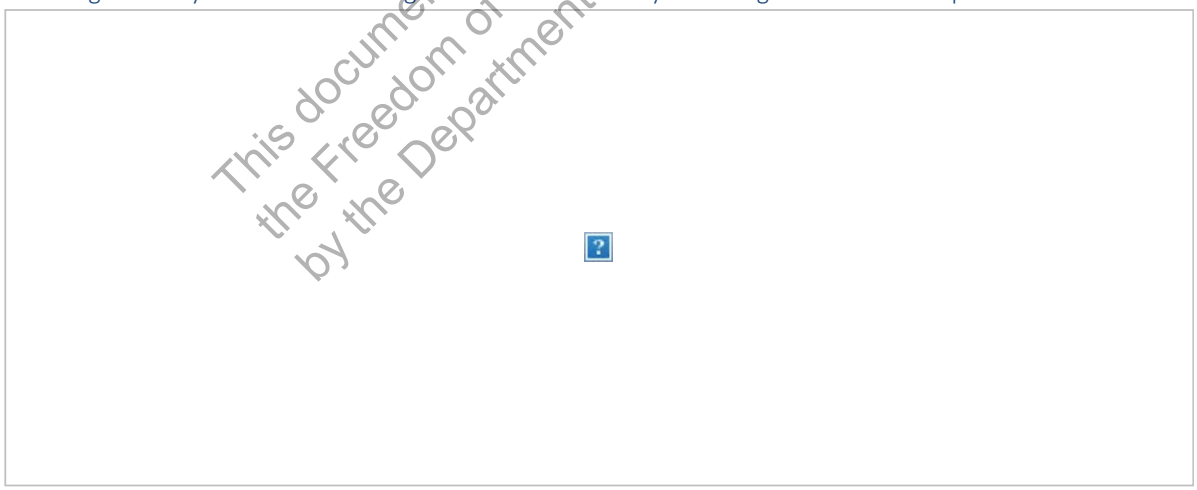
s47E(c), s47F

From: Jane Scott s47F @curtin.edu.au>
Sent: Sunday, 3 November 2024 3:38 PM
To: maif <maif@health.gov.au>
Subject: RE: For Action - DUE 30/10: MAIF Complaints Committee Meeting 17 - Initial determinations table [SEC=OFFICIAL]
Importance: High

Hi s47E(c), s47F
Hopefully you can sort my access out when you get to work on Monday morning. I am attaching the following screenshots so you can forward this to your IT dept.
I do not appear to be in the Health Department directory. This is the message that came up when I tried to log into Sharepoint



When I go into my account I have no guest accounts with any other organizations i.e. Dept of Health



I will dedicate Monday to finishing this. I am so sorry that I didn't at least check that I had access when I first received this message. s22 . I assumed that as I had used it before that all would be good.
Best wishes,
Jane

Jane Scott
PhD, MPH, Grad Dip Diet, BSc, FDAA
Emeritus Professor
Public Health Nutrition
School of Population Health

Curtin University
Tel | s47F

Email | s47F @curtin.edu.au Web | http://curtin.edu.au

PAC-COVID-ReturntoCampus-emailsignaturebanner

From: maif <maif@health.gov.au>
Sent: Tuesday, 29 October 2024 1:38 PM
To: maif <maif@health.gov.au>; WILTON, Kellie s47E(c), s47F @Health.gov.au>; Jonathan Chew s47F @infantnutritioncouncil.com>; Jane Scott s47F @curtin.edu.au>
Subject: RE: For Action - DUE 30/10: MAIF Complaints Committee Meeting 17 - Initial determinations table [SEC=OFFICIAL]

Hi all,

In regard to my email below, it has been brought to my attention that the link to the overarching folder and the links within the initial determination table are not working.

If you are having technically difficulties please try this updated link Meeting 17 - 13 November 2024

Please reach out if you have any further trouble.

Many thanks

s47E(c), s47F
MAIF Complaints Committee Secretariat Team
Nutrition Policy Section

Primary and Community Care Group | Population Health Division
Preventive Health and Food Branch
Australian Government Department of Health and Aged Care
E: MAIF@health.gov.au
MDP 570, GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: maif <maif@health.gov.au>
Sent: Tuesday, 29 October 2024 9:46 AM
To: WILTON, Kellie s47E(c), s47F @Health.gov.au>; Jonathan Chew s47F @infantnutritioncouncil.com>; Jane Scott s47F @curtin.edu.au>
Cc: maif <maif@health.gov.au>
Subject: FW: For Action - DUE 30/10: MAIF Complaints Committee Meeting 17 - Initial determinations table [SEC=OFFICIAL]

Hi Kellie, Jonathan and Jane

We hope you're having a good week.

This is a courtesy reminder that the initial determination table is due COB tomorrow, Wednesday 30

October 2024.

Please reach out if you anticipate any difficulty meeting that timeframe.

Many thanks

s47E(c), s47F

MAIF Complaints Committee Secretariat Team

Nutrition Policy Section

Primary and Community Care Group | Population Health Division

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duplicate of document 10

duplicate of document 10

From: WILTON, Kellie
To: maif
Cc: s47E(c), s47F
Subject: RE: For Chair Review by 6 Nov - MAIF Complaints Committee Agenda Papers [SEC=OFFICIAL]
Date: Wednesday, 6 November 2024 10:06:59 AM
Attachments: image001.png
image002.png

Hi s47E(c), s47F

Looks all good to me. Thank you

Adjunct Associate Professor Kellie Wilton (Midwife) (she/her)
Senior Midwifery Advisor
Bmidwif(UniSA), GradCertIntlHealth(Curtin), GradCertClinEd (Flin),
MPrimaryMaternityCare(Griff), MHML MPH (UNSW)
PhD Candidate (Monash), MACM
Chief Nursing and Midwifery Officer Division | Health Resourcing Group
E: s47E(c), s47F @health.gov.au
M: s47F

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: maif <maif@health.gov.au>
Sent: Monday, 4 November 2024 4:26 PM
To: WILTON, Kellie s47E(c), s47F @Health.gov.au>
Cc: maif <maif@health.gov.au>; s47E(c), s47F @Health.gov.au>
Subject: For Chair Review by 6 Nov - MAIF Complaints Committee Agenda Papers [SEC=OFFICIAL]

Hi Kellie

As discussed with you at our last catch up in late October, we would be grateful for your review of the attached draft agenda papers and annotated agenda for the upcoming MAIF Complaints Committee Meeting on 13 November 2024:

1. Draft Agenda – MAIF Complaints Committee Meeting 17
2. Draft Agenda Papers – MAIF Complaints Committee Meeting 17 includes Attachment A-F.
3. Draft Chair's Annotated Agenda - MAIF Complaints Committee Meeting 17

Subject to your approval, we are aiming to send out the Agenda papers by end of the day, **Wednesday 6 Nov 24**. This is to allow all members one week to consider prior to the meeting.

Regarding the Chairs annotated agenda, we wanted to provide this to you in advance for your consideration and is for further discussion at our pre-meeting catch up on Friday 8 Nov 24 at 2:30pm.

We apologise for the delay getting these papers over to you. This was due to delays in receiving Jane's initial determinations. If you have questions, please don't hesitate to reach out.

Please note that on the meeting day, myself and s47E(c), s47F (who has recently joined the

MAIF team) will be in the Canberra office. Both s47E(c) s47F and s47E(c) s47F will be attending online.

Thanks,
s47E(c), s47F

MAIF Complaints Committee Secretariat Team
Nutrition Policy Section

Primary and Community Care Group | Population Health Division
Preventive Health and Food Branch
Australian Government Department of Health and Aged Care
E: MAIF@health.gov.au
MDP 570, GPO Box 9848, Canberra ACT 2601, Australia

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From: maif
To: WILTON, Kellie; Jonathan Chew; Jane Scott; s47E(c), s47F
Subject: MAIF Complaints Committee - Meeting 17 [SEC=OFFICIAL]
Attachments: image001.png

Hi Kellie, Jonathan and Jane

Please see the updated details for the MAIF Complaints Committee – Meeting 17 to be held face to face in Canberra on Wednesday 13 November 2024, 2:30-4:30pm. Address, Yaradhang Building, 23 Furzer Street, Phillip, ACT, 2606.

Timing

Agenda Item

Supporting Documents

2.30

(5mins)

1

Welcome and acknowledgement of country

Nil

2.35

(5mins)

2

Update of Declaration of Interest Register and agreement to publish

2.40

(5mins)

3

Meeting 16 (20 October 2023)

a. Action Items

2.45

(5mins)

4

Complaints from previous meeting – for noting

2.50

(25mins)

5

New Complaints

a. New in scope/ Not yet determined
b. New complaints – Determined out of session – for noting

Attachment A

3.15

(30mins)

6

MAIF Guidance Documents

a. Clause 7 Guidance
b. Electronic Media Guidance

Attachment B, C, D, E, F

BREAK – 3.45 (10mins)

3.55

(5mins)

7

Department Updates

4.00

(25mins)

8

Committee matters

a. Publishing of complaints on MAIF website
b. Committee Membership Update
c. Annual reports

4.25

(5mins)

9

Other Business

a. Next Meeting Date – Feb 2025

4.30

10

Meeting Close

We look forward to seeing you all then.

Many thanks

s47E(c) 47F
MAIF Complaints Committee Secretariat Team

Nutrition Policy Section

Primary and Community Care Group | Population Health Division

Preventive Health and Food Branch

Australian Government Department of Health and Aged Care

E: MAIF@health.gov.au <mailto:MAIF@health.gov.au>

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Video ID: s22

More info <https://www.webex.com/msteams?confid=1368022535&tenantkey=health-au&domain=m.webex.com>

For organizers: Meeting options s22

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Privacy and security <https://www.health.gov.au/using-our-websites/website-privacy-policy/privacy-notice-for-ms-teams-recordings-and-transcripts>

Marketing in Australia of Infant Formulas (MAIF) Agreement
Complaints Committee Meeting 17

13 November 2024

2.30pm – 4.30pm (AEDT)

Secretariat phone: (02) 6289 7358
Secretariat email: maif@health.gov.au

Agenda

Timing		Agenda Item	Supporting Documents
2.30 (5mins)	1	Welcome and acknowledgement of country	Nil
2.35 (5mins)	2	Update of Declaration of Interest Register and agreement to publish	
2.40 (5mins)	3	Meeting 16 (20 October 2023) a. Action Items	
2.45 (5mins)	4	Complaints from previous meeting – for noting	
2.50 (25mins)	5	New Complaints a. New in scope/ Not yet determined b. New complaints – Determined out of session – for noting	Attachment A
3.15 (30mins)	6	MAIF Guidance Documents a. Clause 7 Guidance b. Electronic Media Guidance	Attachment B, C, D, E, F
BREAK – 3.45 (10mins)			
3.55 (5mins)	7	Department Updates	
4.00 (25mins)	8	Committee matters a. Publishing of complaints on MAIF website b. Committee Membership Update c. Annual reports	
4.25 (5mins)	9	Other Business a. Next Meeting Date – Feb 2025	
4.30	10	Meeting Close	

Item 1 -chair welcomed everyone by name and location to the meeting and completed acknowledgement to country, **confidentiality requirements**
Item 2 | Update of Declarations of Interest register and agreement to publish (2.35pm)
Member to advise of any updates on conflicts of interest.

The current declarations of interest:

Member	Background and experience	Declarations of interest
Kellie Wilton – Independent representative (Chair)	Midwifery Advisor to the Department of Health and Aged Care Chief Nursing and Midwifery Officer	Former employment at the Australian College of Midwives managing the Baby Friendly Health Initiative (BFHI) program. Declared August 2024
Jane Scott – Public health representative	Former Deputy Head of the School of Public Health at Curtin University.	Recipient of an Australian Government Department of Health, Child and Youth health grant to trial 'Milk Man', a breastfeeding app for fathers from rural and remote Western Australia. Co-investigator on a National Health and Medical Research Council (NHMRC) Project Grant led by the University of Queensland. Chair of the recently formed Australian Breastfeeding Association WHO Code Taskforce. Declared October 2021
Jonathan Chew – Industry representative	Infant Nutrition Council (INC) Chief Executive Officer (CEO)	INC CEO Declared August 2024

Kellie has accepted the Chief nursing and midfery officer Northern territory – some hospital services Kellie will be overseeing ay be BFHI hospitals

Jonathan and Jane nil

Item 3a | Meeting 16 (20 October 2023) – Action Items (2.40pm)

Item	MAIF Complaints Meeting (Date)/ Agenda Item	Action	Who	When	Status
1	**Meeting 15: 19 April 2023** Item 5 Complaints previous meeting	Secretariat to consider the guidance updates for cross national promotion.	Secretariat	20 Nov 2023	**Closed** - to be considered in the review of MAIF guidance document: Electronic Media (Agenda Item 6b). noted
2	**Meeting 15: 19April 2023** Item 6 New complaints	Secretariat to note the Therapeutic Goods Administration's social media advertising guide when considering testimonial social media advice.	Secretariat	20 Nov 2023	**Closed** - to be considered in the review of MAIF guidance document: Electronic Media (Agenda Item 6b). noted
3	**Meeting 16: 20 October 2023** Item 3b Meeting 15 (19 April 2023) Action Items	Committee to provide any comments on the summary of the signatories forum. Once comments are provided, Secretariat to send the summary of the signatories forum to the Signatories.	Committee/Secretariat	3 Nov 2023	**Complete** - Secretariat finalised the signatories forum summary and distributed with a committee update. noted
4	**Meeting 16: 20 October 2023** Item 4 Complaints from previous meeting – for final determination	Secretariat to update guidance to include a limitation on timeframes. Suggested wording to be considered, as provided by the Chair.	Secretariat	20 Nov 2023	**Closed** - to be considered in the review of MAIF guidance document: Electronic Media (Agenda Item 6b). noted
5	**Meeting 16: 20 October 2023** Item 5 New complaints	Secretariat to provide guidance to signatories regarding change in stock or availability communications.	Secretariat	20 Nov 2023	**Closed** - to be considered in the review of MAIF guidance document: Electronic Media (Agenda Item 6b). noted
6	**Meeting 16: 20 October 2023** Item 6 MAIF guidance documents – Clause 7 guidance document	Committee to provide final comments within a week of Meeting 16 (20 Oct) on Clause 7 guidance documents.	Members	27 Oct 2023	**In Progress** - Committee endorsed the documents with one final review of wording relating to competitions needed. Updated wording for members consideration at Agenda Item 6a. noted

Item 4 | Complaints from previous meeting (2.45pm) **noted – jane expressed strong views on why the complaints were not sent off,** s47E(c), s47F **acknowledged the issue and apologised to jane and expressed that our future direction is to improve these processes.**

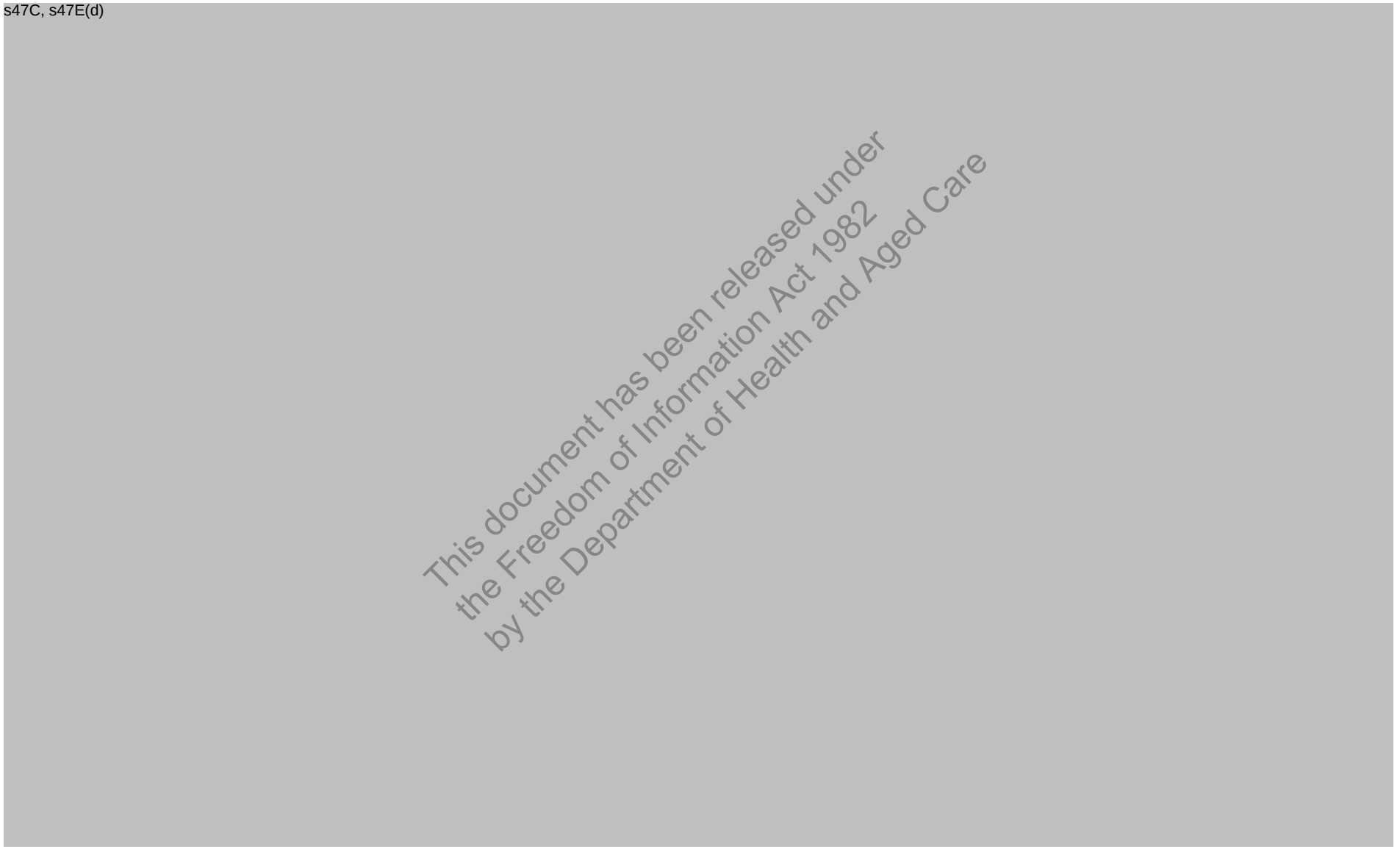
Members to note the following complaints have been finalised since the previous meeting (Meeting 16, 20 October 2023).

Complaint Reference	Company	Final Determination	Final determination letters	
			Complainant	Company
2223-35	s47G	No Breach	Complete	Complete
2223-52	The LittleOak Company	Breach	Complete	Complete
2223-54	The LittleOak Company	Breach	Complete	Complete
2223-55	Sprout Organic	Breach	Complete	Complete
2223-57	The LittleOak Company	Breach	Complete	Complete
2223-65	s47G	Out of Scope	Complete	N/A
2223-78		Out of Scope	Complete	N/A
2223-79		Out of Scope	Complete	N/A
2223-83	The LittleOak Company	Breach	Complete	Complete
2223-84	Sprout Organic	Breach	Complete	Complete
2223-87, 89, 90, 91, 92	Sprout Organic	Breach	Complete	Complete
2223-93	s47G	Out of Scope	Complete	N/A
2223-94		Out of Scope	Complete	N/A
2223-95		No Breach – scope un-determined	Complete	Complete
2223-96	Sprout Organic	Breach	Complete	Complete
2223-97	Australian Dairy Nutritionals	Breach	Complete	Complete
2223-98	Australian Dairy Nutritionals	Breach	Complete	Complete
2223-99	Australian Dairy Nutritionals	Breach	Complete	Complete
2223-100	Sprout Organic	Breach	Complete	Complete

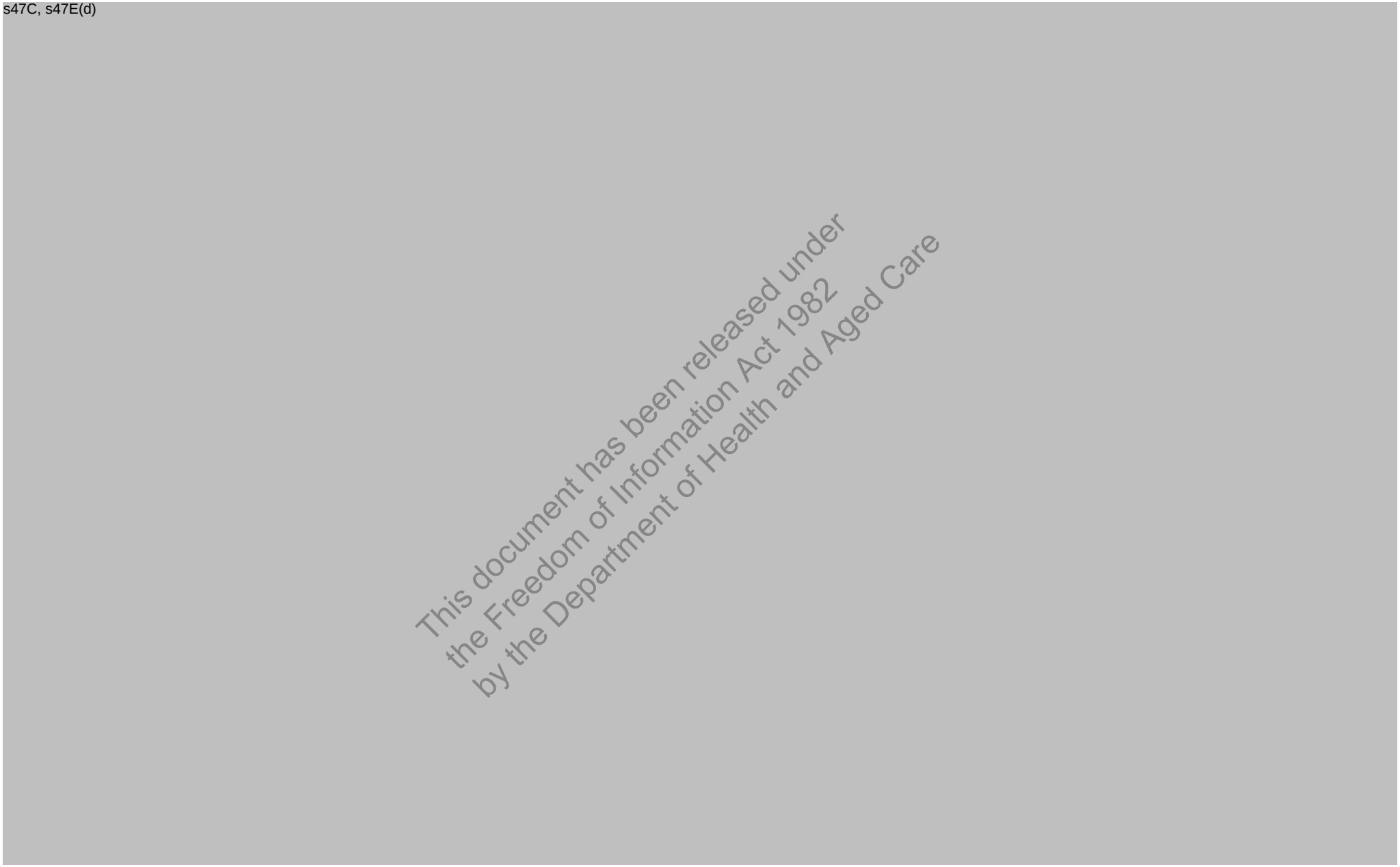
Item 5a | New complaints – New in-scope or not yet determined (2.50pm)

Members to deliberate on complaints and make final determinations. Refer to **Attachment A** for the collated complaint forms and company responses.

s47C, s47E(d)

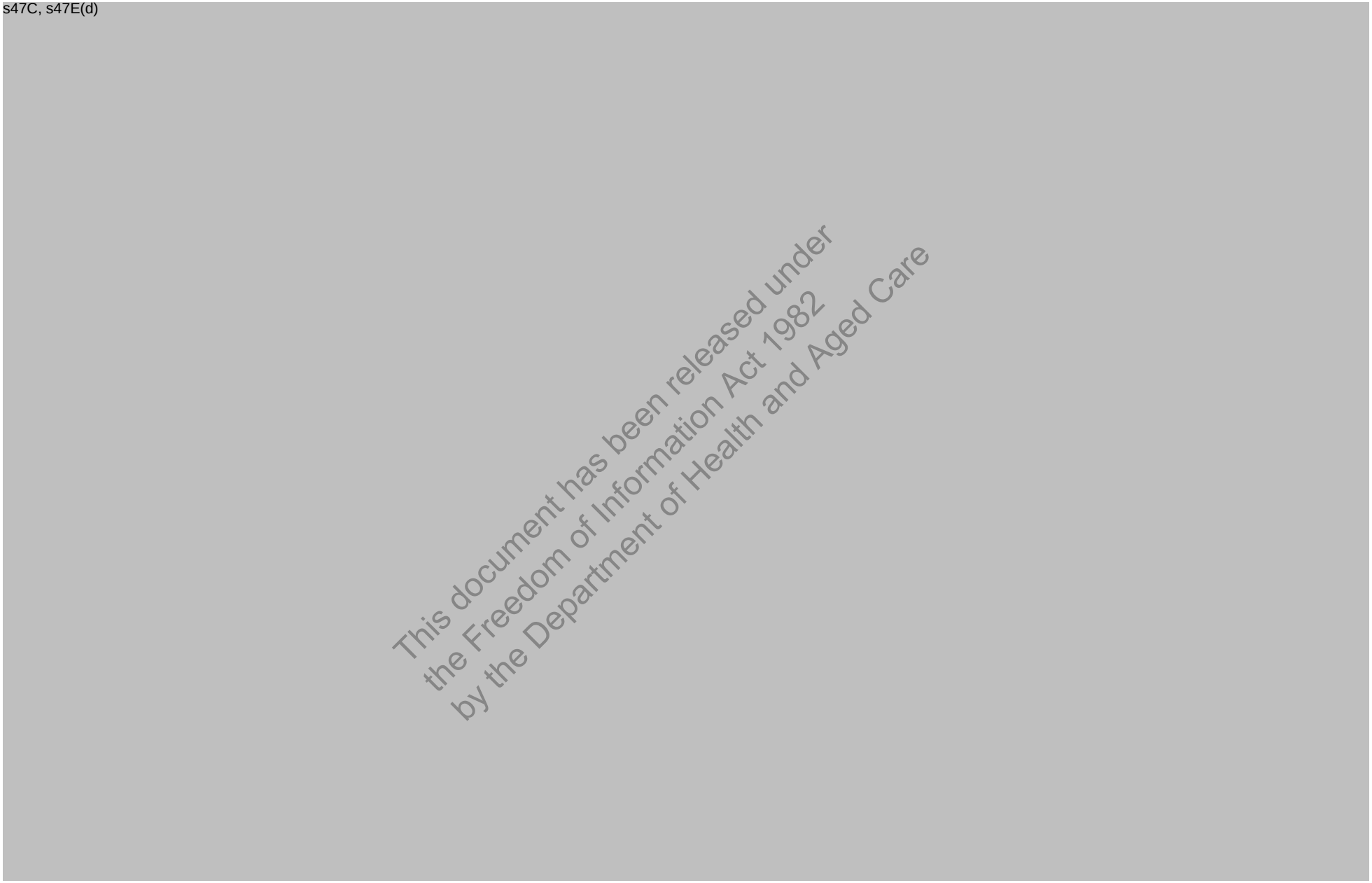


s47C, s47E(d)

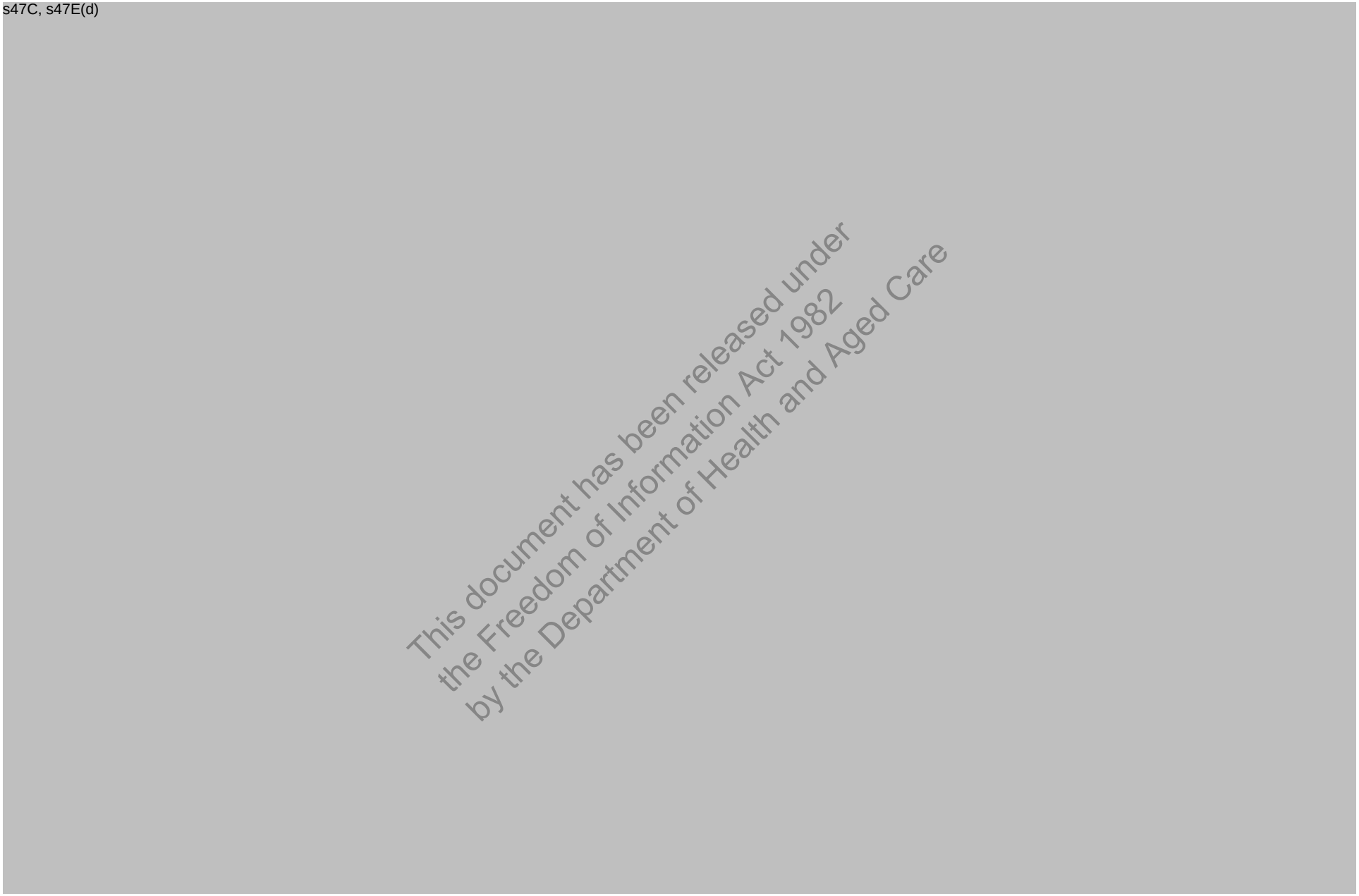


s47C, s47E(d)

s47C, s47E(d)



s47C, s47E(d)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s47C, s47E(d)


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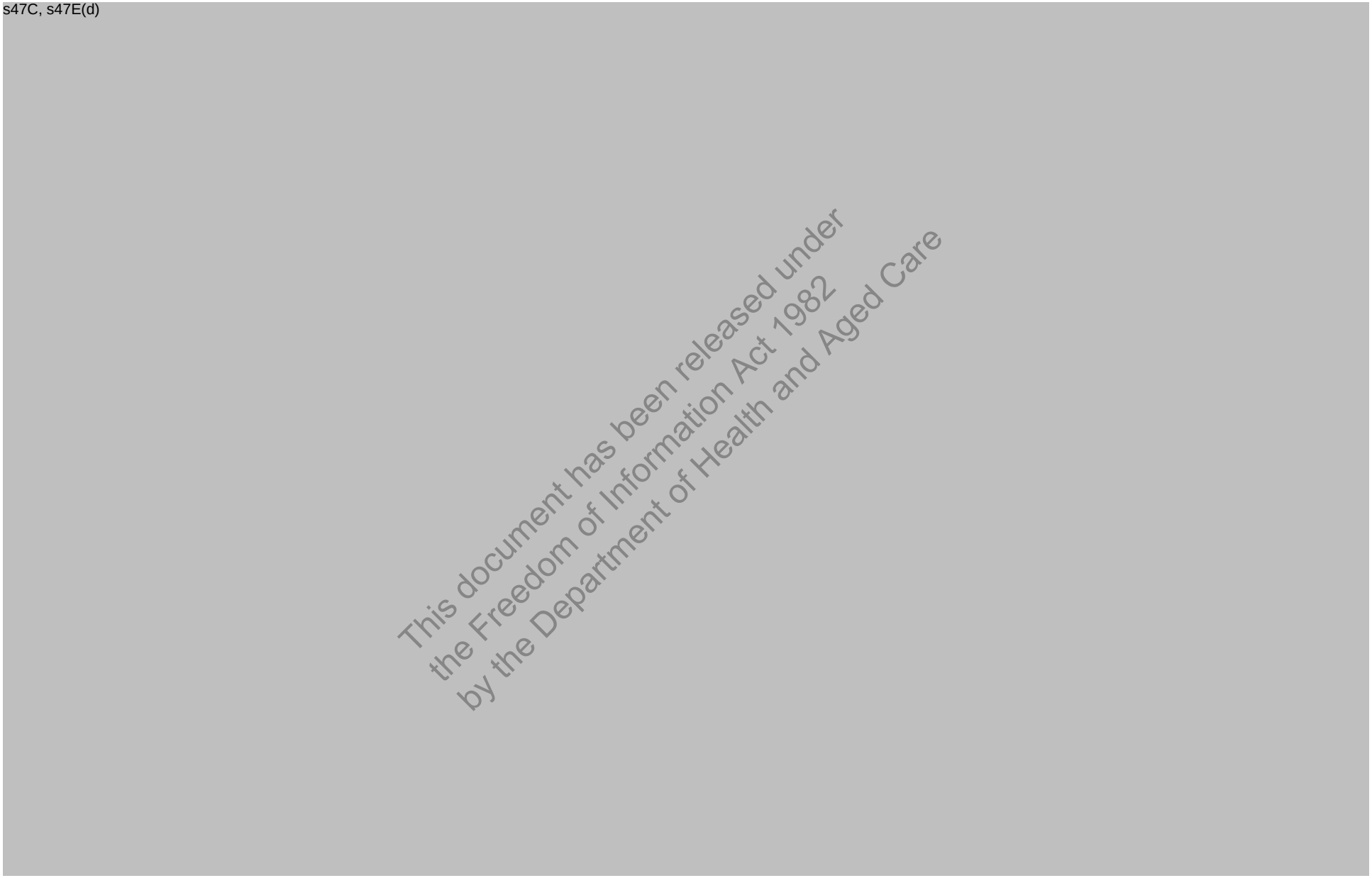
s47C, s47E(d)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s47C, s47E(d)

Item 5b | New complaints – Determined out of session – for noting s47C, s47E(d)

Of the 19 new complaints reviewed out of session by members

- Members agreed on the final determination for 12 of the complaints.
- 1 complaint deemed a breach and 11 deemed out of scope by members.

Complaint Reference	Company	Final Determination/Reason	Final determination letters	
			Complainant	Company
2324-01	s47G	Out of scope – Toddler milk	In progress	In progress
2324-06	The LittleOak Company	Breach	In progress	In progress
2324-08	s47G	Out of scope – Retailer	Complete	N/A
2324-09		Out of scope – Toddler milk	Complete	N/A
2324-10		Out of scope – Non signatory	Complete	N/A
2324-11		Out of scope – Non signatory	Complete	N/A
2324-12		Out of scope – Non signatory	Complete	N/A
2425-01		Out of scope – Non signatory	Complete	N/A
2425-03		Out of scope – Retailer	Complete	N/A
2425-04		Out of scope – Retailer	Complete	N/A
2425-05		Out of scope – Retailer/toddler milk	Complete	N/A
2425-06		Out of scope – Non signatory	Complete	N/A

Item 6 | MAIF guidance documents (3.15pm)

Item 6a | Clause 7 Guidance:

That Members:

- **Note** the background regarding Clause 7 Guidance Document (Clause 7 Document).
- **Discuss** the Clause 7 Guidance Document at **Attachment B** and whether additional amendments should be made to align advice on 'Competitions'.

Background:

- Guidance on Clause 7 limits the type of information that signatories can provide to health care professionals on infant formula products.
- At the last meeting (20 October 2023), Members endorsed updates to the Clause 7 Guidance but requested that Secretariat consider the wording around 'competitions' which allows for prizes of a low value not exceeding $100 (point under sub-heading 'Inducements').
- Guidance by Medicines Australia (see **Attachment C**, Section 2.7 Competitions), notes that competitions may be run by member companies, but no prizes may be offered.
- The following change to the Clause 7 Guidance Document would achieve alignment with the Medicines Australia approach:
    - Competitions, included in information material for health professionals, which are clearly for the purpose of emphasising scientific and factual information only, may be acceptable. Such competitions should not be an inducement to promote infant formulas. No prize or gift may be offered under any circumstances.

s47C, s47E(d)

[redacted]

Item 6b | Electronic Media Guidance:

That Members:

- **Note** the background regarding the Electronic Media Guidance Document (Electronic Media Guidance).
- **Discuss** the Electronic Media Guidance at **Attachment D** and workshop initial reactions and agree next steps, including providing direction to the Department on preferred activities to support this work and timeframes for implementation.

s47C, s47E(d)

[redacted]

s47C, s47E(d)

[redacted]

Background:

- The Electronic Media Guidance provides guidance on the application of the MAIF Agreement to activities undertaken on electronic media including social media.
- Work to amend the guidance to clarify the application of the MAIF Agreement in these contexts has been on hold pending the finalisation of the independent review undertaken by Allen + Clarke Consulting.
- As outlined in the Department's submission to the Australian Competition and Consumer Commission (ACCC) Draft Determination, the Department has committed to working with the MAIF Complaints Committee to update the Electronic Media Guidance to clarify that social media promotion, including social media influencing, is subject to the MAIF Agreement.

- In its submission, the Department also acknowledged that since the development of this guidance there has been developments in other areas, which were highlighted in the submission, namely:
    - the WHO has developed guidance on regulatory measures aimed at limiting the digital marketing of breast-milk substitutes (**Attachment E**), and
    - the Therapeutic Goods Administration (TGA) has published the 'Advertising Code' that sets standards for advertising therapeutic goods, including on social media (**Attachment F**).
- Based on previous engagements, Signatories have suggested clearer definitions would be helpful and that the guidance provide greater detail on:
    - the definition of what a paid influencer is;
    - hash tag use, and
    - sharing and re-sharing content
- There is currently no advice on timeframes around social media complaints received. The Committee have previously discussed updating guidance to signatories on complaint timeframes and suggested the below wording:
    - 'Complaints should have an incident date within the past 12 months. Complaints be submitted within 3 months of the incident. Complaints where the incident has occurred over 12 months ago will not be considered. For complaints relating to social media please take a screen shot of the complaint with a timestamp attached.'
- Below are examples of past complaints related to social media that were found to be in breach of the MAIF Agreement:

Issues	**Context**
Use of social media "stories"	Use of social media stories which only appear for a short window of time (e.g. 24 hours) before disappearing from the company's social media page. Advertising and promotion of infant formula, even if it is only available for viewing temporarily is still considered a breach of the MAIF Agreement.
Images which depict infants	Images which depicts infants even without specific mention of infant formula.
Re-posted images and text	Re-posted images and text promoting infant formula on the signatory's social media pages, even if they didn't originate from the signatory's social media accounts, can be considered a breach of the MAIF Agreement. For example, sharing or re-posting a mother's post including a mothers product testimonial, blog post relating to infant formula and breastfeeding.
Videos or images posted on social media, original or re-shared	Videos or images posted on social media, original or re-shared which don't specifically discuss or reference infant formula but have infant formula images in the background of the video/image.

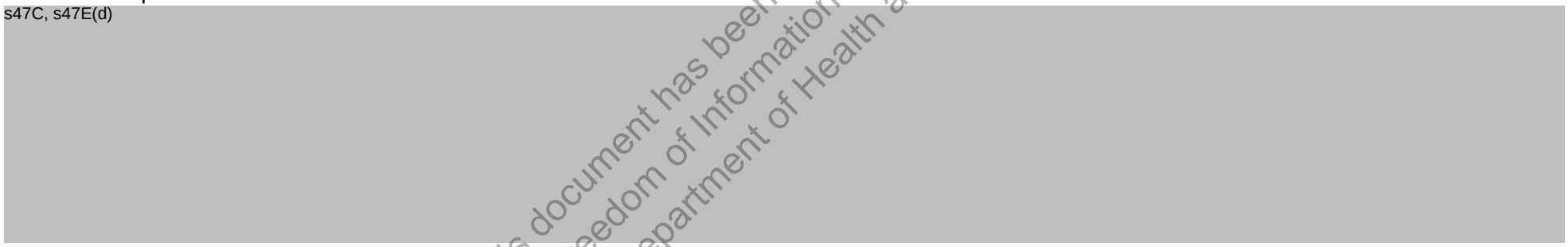
The use of hashtags and wording on posts, images and videos (captions)	Hashtags or captions which promote infant formula products, can be used by members of the public to search for topics and posts of interest. If your post is about toddler milk products, buta hashtag that refers to babies, infant feeding, infant formula etc. is included – this can still constitute a breach of the MAIF Agreement.
Advertising discounts on entire range which includes infant formula	Discounts advertised for entire product range and not specifying which products are part of the discount sale is misleading and inadvertently promotions infant formula products.
Testimonial posts	Testimonial posts which are either re-shared or directly posted to a signatories' social media site if referring to infant formula products, breastfeeding journeys, blog posts that are promotional of infant formula are considered to be a breach of the MAIF Agreement. The TGA social media guidance may have further information on this.
Change in stock	It is acceptable to notify the public that a product is back in stock for a limited time period using non-promotional information only. Advertising a product is 'now available' (example: at a new location) is considered a breach of the MAIF Agreement.
Posting of Infant formula content/information on social media	Examples of this are FAQ's and Q&A responses from signatories' websites that are posted to Instagram stories from but do not have the breastfeeding statement preface. Without the breastfeeding statement this is a breach.
Cross national promotion	Sharing posts from international branches of a signatory's company that include infant formula references (image, wording, product ranges), other examples include a signatory advertising that they are expanding their product range into international markets (Item 1 in the action table)
Sponsored advertising on social media of infant formula	A sponsored post is a social media post that a company has paid to promote. Sponsored advertising of infant formula is promotional and a breach of the MAIF Agreement.
Promoting a product award	Specifically for infant formula awards - posts notifying the public of a company's award-winning product, similarly that an award has been won for an infant formula product. This type of post is not for educational purposes and is considered promotional and a breach of the MAIF Agreement.

Item 7 | Departmental Updates (3:55pm)

Members to note the below Departmental updates:

- The Department has provided a submission to the ACCC draft determination process supporting re-authorisation of the MAIF Agreement for two years.
- As outlined in the Departments submission, the Australian Government is committed to mandating the MAIF Agreement, proposing a two-year timeframe to put mandatory controls in place.
- In the interim, the Government has committed to practical steps to strengthen the voluntary arrangement during the transition period, in line with recommendations from the MAIF Agreement Review:
    - Strengthen the digital marketing guidance in collaboration with the MAIF Complaints Committee
    - Investigate technology-enabled solutions for monitoring digital marketing
    - Expand the MAIF Complaints Committee to include one additional independent member
    - Uplift the governance arrangements to support greater transparency and timeliness of decision-making including quarterly committee meetings, publishing meeting dates in advance, improving the complaints process, updating committee governance documents available on the Department's website and explore the viability of a live decisions dashboard of incoming complaints. The Department also committed to undertaking quarterly monitoring of compliance with the MAIF Agreement to reduce the burden on members of the public and interested parties.

s47C, s47E(d)



Item 8 | Committee matters (4:00pm)

Item 8a| Publishing of complaints on the MAIF website

Members to comment on the appropriateness, or otherwise, of publishing final complaint outcomes from Meeting 16 (15 October 2023).

s47C, s47E(d)

[redacted]

Background:

- On 26 September 2024, the Secretariat finalised and sent the final determination letters following the decisions of the last MAIF Complaints Committee Meeting 16 held on 15 October 2023. s 47G replied seeking the Department not to publish its breaches on the website noting issues with the timeliness and transparency of the complaints handling process and time conceded. s 47G alleges matters were either rectified or removed well before the complaint was even lodged and publishing would be defamatory.
- The timeline of the complaints s 47G refers is outlined below:

s 47G

[redacted]

s 47G [redacted]

- The Department will consider Members views, internal Health Legal advice and other relevant factors in making a final decision on this matter.

Comiitee acknowledged s 47G concerns

Key points

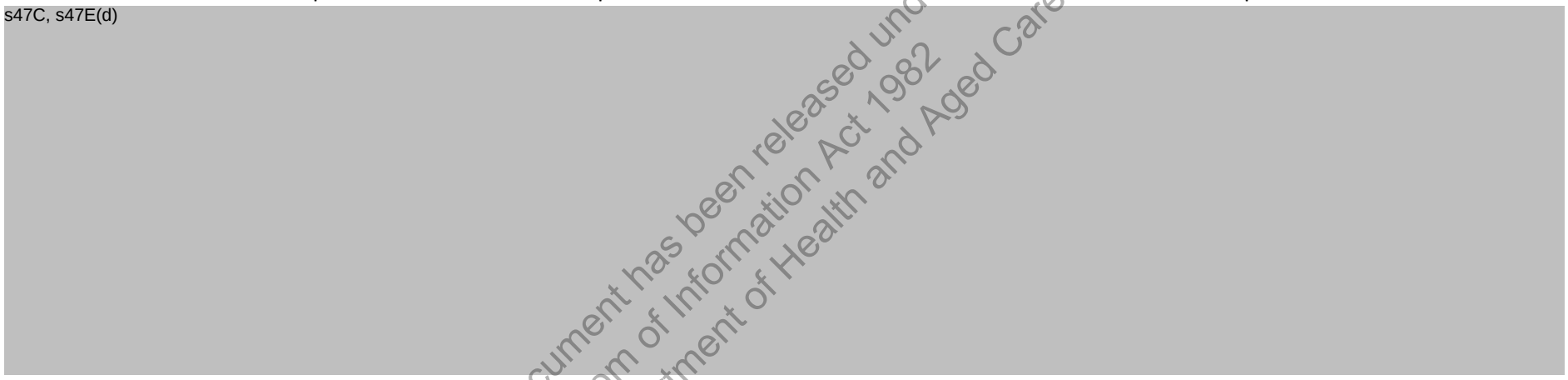
Action: secretairt to consider this forward acknowledging committee concerns.

Item 8b| Committee Membership Update

That Members:

- **Note** as part of strengthening the voluntary arrangements and consistent with the MAIF Review, the MAIF Complaints Committee will be expanded.
- **Discuss** the desired skill set required for the additional independent member and recommend suitable candidates for the Department's consideration.

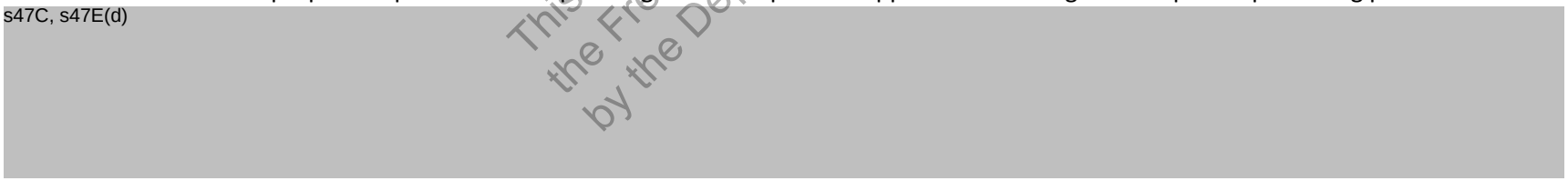
s47C, s47E(d)



Item 8c| Annual Reports

Members to discuss the proposed updates to the upcoming Annual Report to support streamlining the complaints publishing process.

s47C, s47E(d)



Background:

- Complaint outcomes are published on the Department's website here and in the Annual Reports here. Currently, the Department's website only displays the current financial year complaints and previous complaint details are found in the Annual Reports. The normal process is for all complaints to be published on the department's website following committee final determination. The complaints are then summarised a second time and published in the Annual Reports (released every financial year).
- The Secretariat is yet to prepare the 2023-24 Annual Report.
- Secretariat propose changing the structure of the upcoming 2023-24 Annual Report (and beyond) to remove the table summary of each complaint. Instead detailed per complaint outcomes would be retained on the Department's website. This approach would streamline the annual reporting process, reduce duplication and free up Secretariat resources for higher impact work.

Item 9 | Other Business (4.25pm)
Item 9a| Next meeting date
Members to discuss and agree on meeting dates for 2025 to be held virtually.

Suggested to be on the third Wednesday of every month unless members are unavailable.

- 19 February 2025
- 21 May 2025
- 20 August 2025
- 19 November 2025

s47C, s47E(d)

[redacted]

s47C, s47E(d)

[redacted]

s47C, s47E(d)

[redacted]

Attachments:

Attachment A – New Complaints for further discussion

Attachment B – Clause 7 Guidance Document

Attachment C – Excerpt of Medicines Australia Code of Conduct Guidelines – Section 2.7 Competitions.

Attachment D – MAIF Electronic Media Guidance Document.

Attachment E – WHO Guidance on regulatory measures aimed at restricting digital marketing of breast-milk substitutes

Attachment F – TGA electronic media guidance

From: s47E(c), s47F
To: WILTON, Kellie
Cc: maif; s47E(c), s47F
Subject: For clearance: MAIF Complaints Committee - Meeting 17 - Final determination letters [SEC=OFFICIAL]
Date: Thursday, 5 December 2024 3:44:57 PM
Attachments: image001.png
image002.png

Hi Kellie

As discussed, seeking your clearance please for the final determination letters from MAIF Complaints Committee - Meeting 17, SharePoint links below:

- Company Letters
- Complainant Letters

Next Steps:

- Once we receive your clearance, I will apply the date and your e-signature. Following this the letters will be emailed as a PDF to the relevant addressee.
- Secretariat will then progress the Meeting 17 determinations for publishing on the Department's website here.

Please reach out if you have any further questions.

Many thanks

s47E(c), s47F
Nutrition Policy Section
Preventative Health & Food Branch
Population Health Division | Primary & Community Care Group
Australian Government, Department of Health and Aged Care
T: 02 s47E(c), s47F | E: s47E(c), s47F @health.gov.au
Location: Yaradhang Building 5.S.231
GPO Box 9848, Canberra ACT 2601, Australia
The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present

MAIF Complaints Committee
GPO Box 9848
Canberra ACT 2601
maif@health.gov.au
www.health.gov.au/maif

s47F

Marketing in Australia of Infant Formulas: Manufacturers and Importers (MAIF) Agreement
Final Determinations – Complaint: 2324-01

Dear s47F

I am writing to advise you of the outcome of the MAIF Complaints Committee (the Committee) determination of the above referenced complaint, received in September 2023.

The Committee considered the complaint on 13 November 2024 at MAIF Complaints Committee Meeting 17 and made the following determination:

- **2324-01** s47G the alleged breach of clause 5 was determined to be **out of scope** of the MAIF Agreement, noting the complaint relates to promotion of a toddler milk product.

The Committee has written to s47G to advise of the determination in relation to the MAIF Agreement.

Thank you for taking the time to submit this complaint. If you have any questions or require further information, please contact the MAIF Secretariat on (02) 6289 7358 or maif@health.gov.au.

Yours sincerely
s47F
Adjunct Associate Professor Kellie Wilton
Chair
MAIF Complaints Committee

11 December 2024

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s47F

Marketing in Australia of Infant Formulas: Manufacturers and Importers (MAIF) Agreement
Final Determinations – Complaint: 2324-02, 2324-03

Dear s47F

I am writing to advise you of the outcome of the MAIF Complaints Committee (the Committee) determination of the above referenced complaints, received in September 2023.

The Committee considered the complaints on 13 November 2024 at MAIF Complaints Committee Meeting 17 and made the following determinations:

- **2324-02 Bellamy's Organic:** was determined **in breach** of clause 5(a) of the MAIF Agreement. The Committee agreed that Bellamy's Organic could have taken further action to clarify the ambiguous wording used in the promotion to ensure that infant formula was not promoted.
- **2324-03 Sprout Organic:** was determined **in breach** of clause 5(a) of the MAIF Agreement as the company used images of infant formula tins in their crowdfunding post. The Committee noted alternate images could have been used instead to promote the crowdfunding campaign.

The Committee has written to Bellamy's Organic and Sprout Organic to advise of the determinations in relation to the MAIF Agreement.

Thank you for taking the time to submit these complaints. If you have any questions or require further information, please contact the MAIF Secretariat on (02) 6289 7358 or maif@health.gov.au.

Yours sincerely

s47F

Adjunct Associate Professor Kellie Wilton
Chair
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11 December 2024

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s47F

Marketing in Australia of Infant Formulas: Manufacturers and Importers (MAIF) Agreement
Final Determinations – Complaint: 2324-04, 2324-05, 2324-06, 2324-07, 2425-05

Dear s47F

I am writing to advise you of the outcome of the MAIF Complaints Committee (the Committee) determination of the above referenced complaints, received between October 2023 and August 2024. I apologise for the delay in making this information available to you and appreciate your patience during this time.

The Committee considered the complaints on 13 November 2024 at MAIF Complaints Committee Meeting 17 and made the following determinations:

- **2324-04 Sprout Organic**: was determined **in breach** of clause 5(a) of the MAIF Agreement as the company used images of a father holding an infant and an infant formula tin in their crowdfunding email. The Committee note alternate images could have been used to promote the crowdfunding campaign, thereby ensuring that infant formula was not promoted. In relation to the alleged breach of Clause 5(d) the Committee determined no breach on this occasion.
- **2324-05 The LittleOak Company**: was determined **in breach** of clause 5(a) of the MAIF Agreement due to the use of infant formula tins at the event and pictured on social media. The Committee determined the alleged breach of clause 5(c) to be in-scope - undetermined due to insufficient information on the contents of the goodie bag. The alleged breach of clause 5(d) was determined to be in-scope - s47E(d)
- **2324-06 The LittleOak Company**: was determined **in breach** of clause 5(a) of the MAIF Agreement due to the promotion of new ready to drink goat milk infant formula product that included comparisons to breastmilk during an ABC radio interview with the company CEO.
- **2324-07 Bellamy's Organic:** The Committee acknowledges there were three parts to the complaint. Incident one – company signage, Incident two – toddler milk promotion and Incident three – promotion of infant formula via signage displayed in Chinese language. The Committee agreed that incident one and incident two, did not breach the MAIF Agreement. Incident three was determined **in breach** of the clause 5 (a) of the MAIF Agreement. The Committee agreed that Bellamy's Organic could have taken further action to clarify the ambiguous wording used in the promotion to ensure that infant formula was not promoted.

- **2425-05** s47G the alleged breach of clause 5(a) was determined **out of scope** of the MAIF Agreement as it relates to the promotion of toddler milk products.

The Committee has written to MAIF signatories to inform them of the determinations in relation to the MAIF Agreement.

Thank you for taking the time to submit these complaints. If you have any questions or require further information, please contact the MAIF Secretariat on (02) 6289 7358 or maif@health.gov.au.

Yours sincerely

s47F

Adjunct Associate Professor Kellie Wilton
Chair
MAIF Complaints Committee

11 December 2024

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s47F

Marketing in Australia of Infant Formulas: Manufacturers and Importers (MAIF) Agreement
Final Determinations – Complaint: 2425-03, 2425-04

Dear s47F

I am writing to advise you of the outcome of the MAIF Complaints Committee (the Committee) determination of the above referenced complaints, received in July 2024.

The Committee considered the complaints on 13 November 2024 at MAIF Complaints Committee Meeting 17 and made the following determinations:

- **2425-03** s47G **:** the alleged breach of clause 5(a) was determined **out of scope** of the MAIF Agreement s47E(d)
- **2425-04** s47G **:** the alleged breach of clause 5(a) was determined **out of scope** of the MAIF Agreement s47E(d)

Thank you for taking the time to submit the complaints. If you have any questions or require further information, please contact the MAIF Secretariat on (02) 6289 7358 or maif@health.gov.au.

Yours sincerely
s47F

Adjunct Associate Professor Kellie Wilton
Chair
MAIF Complaints Committee

11 December 2024

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s47F

Marketing in Australia of Infant Formulas: Manufacturers and Importers (MAIF) Agreement
Final Determination – Complaint: 2425-07

Dear s47F

I am writing to advise you of the outcome of the MAIF Complaints Committee (the Committee) determination of the above referenced complaint, received in September 2024.

The Committee considered the complaint on 13 November 2024 at MAIF Complaints Committee Meeting 17 and made the following determination:

- **2425-07** s47G the alleged breach of clause 7(a) was determined **not a breach** of the MAIF Agreement. While the conduct (providing information about infant formula to health professionals) is in scope of the MAIF Agreement, the Committee found the contents of the email sent to hospital staff to be factual information, that is permitted under clause 7(a).

The Committee has written to s47G to advise of the determination in relation to the MAIF Agreement.

Thank you for taking the time to submit this complaint. If you have any questions or require further information, please contact the MAIF Secretariat on (02) 6289 7358 or maif@health.gov.au.

Yours sincerely

s47F

Adjunct Associate Professor Kellie Wilton
Chair
MAIF Complaints Committee

11 December 2024

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s47F

Marketing in Australia of Infant Formulas: Manufacturers and Importers (MAIF) Agreement
Final Determinations – Complaints: 2324-01, 2425-07

Dear s47F

I refer to the above referenced complaints concerning the alleged breach of the MAIF Agreement by s47G for complaint 2324-01 relating to clause 5 and complaint 2425-07 relating to clause 7(a) of the MAIF Agreement.

The MAIF Complaints Committee (the Committee) considered the complaints and your company's response at its meeting on the 13 November 2024 and made the following determinations:

- **Complaint 2324-01:** the activity by s47G in relation to alleged breach of clause 5 was determined **out of scope** of the MAIF Agreement because the complaint relates to promotion of a toddler milk product. Toddler milk products are not subject to the MAIF Agreement.
- **Complaint 2425-07:** the activity by s47G in relation to the alleged breach of clause 7(a) was determined **not a breach** of the MAIF Agreement. While the conduct (providing information about infant formula to health professionals) is in scope of the MAIF Agreement, the Committee found the contents of the email sent to hospital staff to be factual information, that is permitted under clause 7(a).

Thank you for your efforts in adhering to the requirements of the MAIF Agreement as a MAIF signatory. Please contact the MAIF Secretariat if you have any questions regarding the above information or the MAIF Agreement on 02 6289 7358 or maif@health.gov.au.

Yours sincerely

s47F

Adjunct Associate Professor Kellie Wilton
Chair
MAIF Complaints Committee

11 December 2024

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s47F
Bellamy's Organic
s47F

Marketing in Australia of Infant Formulas: Manufacturers and Importers (MAIF) Agreement
Final Determination - Complaint Reference: 2324-02, 2324-07

Dear s47F,

I refer to the above referenced complaints concerning the alleged breach of clause 5(a) of the MAIF Agreement by Bellamy's Organic. The MAIF Complaints Committee (the Committee) considered the complaints and your company's response at its meeting on the 13 November 2024 and made the following determinations:

- **Complaint 2324-02:** the activity by Bellamy's Organic was determined to be **in breach** of clause 5(a) of the MAIF Agreement. The Committee acknowledge the company response noting there is no word for toddler in the Chinese language. Nonetheless, it was agreed that Bellamy's Organic could have taken further action to clarify the ambiguous wording used in the promotion to ensure infant formula was not promoted.
- **Complaint 2324-07:** the activity by Bellamy's Organic was determined to be **in breach** of clause 5(a) of the MAIF Agreement. There were three parts to the complaint. The Committee agreed that *incident one* - the company signage and *incident two* - the promotion of toddler milk do not breach the MAIF Agreement. However, *incident three* is considered to have breached clause 5(a), per the determination for Complaint 2324-02: due to the failure to clarify the ambiguous wording used in the promotion.

The Bellamy's Organic breach of clause 5(a), in relation to Complaints 2324-02 and 2324-07, will be recorded on the MAIF Complaints Committee website.

The MAIF Secretariat is available to support MAIF signatories in meeting their obligations to the MAIF Agreement and can be contacted on (02) 6289 7358 or maif@health.gov.au.

Yours sincerely
s47F

Adjunct Associate Professor Kellie Wilton
Chair
MAIF Complaints Committee

11 December 2024

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s47F
Sprout Organic
s47F

Marketing in Australia of Infant Formulas: Manufacturers and Importers (MAIF) Agreement
Final Determinations – Complaints: 2324-03, 2324-04

Dear s47F,

I refer to the above referenced complaints concerning the alleged breaches of the MAIF Agreement by Sprout Organic for complaint 2324-03 relating to clause 5(a) and complaint 2324-04 relating to clause 5(a) and 5(d) of the MAIF Agreement.

The MAIF Complaints Committee (the Committee) considered the complaints and your company's response at its meeting on the 13 November 2024 and made the following determinations:

- **Complaint 2324-03:** the activity by Sprout Organic was determined **in breach** of clause 5(a) of the MAIF Agreement due to the use of images of infant formula tins as part of the crowdfunding campaign social media post. The Committee note that alternate images (e.g. toddler milk products) could have been used to promote the crowdfunding campaign.
- **Complaint 2324-04:** the activity by Sprout Organic was determined **in breach** of clause 5(a) of the MAIF Agreement due to imagery used of a father holding an infant and an infant formula tin in the email. The Committee note alternate images could have been used to promote the crowdfunding campaign.
  In relation to the alleged breach of Clause 5(d) the Committee determined no breach on this occasion.

Sprout Organic's breaches of clause 5(a), in relation to Complaints 2324-03 and 2324-04, will be recorded on the MAIF Complaints Committee website.

The MAIF Secretariat is available to support MAIF signatories in meeting their obligations to the MAIF Agreement and can be contacted on (02) 6289 7358 or maif@health.gov.au.

Yours sincerely

s47F

Adjunct Associate Professor Kellie Wilton
Chair
MAIF Complaints Committee

11 December 2024

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s47F
The LittleOak Company
s47F

Marketing in Australia of Infant Formulas: Manufacturers and Importers (MAIF) Agreement
Final Determinations – Complaints: 2324-05, 2324-06

Dear s47F,

I refer to the above referenced complaints concerning alleged breaches of the MAIF Agreement by The LittleOak Company for complaint 2324-05 relating to clause 5(a), 5(c), 5(d) and complaint 2324-06 relating to clause 5(a) of the MAIF Agreement.

The MAIF Complaints Committee (the Committee) considered the complaints and your company's response at its meeting on the 13 November 2024 and made the following determinations:

- **Complaint 2324-05:** the activity by The LittleOak Company was determined **in breach** of clause 5(a) of the MAIF Agreement due to the use of infant formula tins at the event and pictured on social media. The Committee determined the alleged breaches of clause 5(c) and 5(d) to be in-scope but undetermined. In relation to clause 5(c) there was insufficient information regarding the contents of the goodie bag. In relation to clause 5(d), the Committee were unable to determine if there were marketing personnel present at the event.
- **Complaint 2324-06:** the activity by The LittleOak Company was determined **in breach** of clause 5(a) of the MAIF Agreement due to the promotion of new ready to drink goat milk infant formula product that included comparisons to breastmilk, during an ABC radio interview.

The LittleOak Company breaches of clause 5(a), in relation to Complaints 2324-05 and 2324-06, will be recorded on the MAIF Complaints Committee website.

The MAIF Secretariat is available to support MAIF signatories in meeting their obligations to the MAIF Agreement and can be contacted on (02) 6289 7358 or maif@health.gov.au.

Yours sincerely
s47F

Adjunct Associate Professor Kellie Wilton
Chair
MAIF Complaints Committee

11 December 2024

s22

From: Jonathan Chew s47F @infantnutritioncouncil.com>
Sent: Wednesday, 4 December 2024 8:55 AM
To: KRIST, Karen
Cc: s47E(c), s47F
Subject: Re: Request for chat - WHO EB meeting - digital marketing [SEC=OFFICIAL]

Thanks, s47E(c), s47F

I'm free Monday 11-3.30 or Wednesday 10-12 or 3-5pm. Let me know if there's a 30 minute window that may suit.

Cheers
Jonathan

From: s47E(c), s47F @Health.gov.au>
Date: Wednesday, 4 December 2024 at 8:26 AM
To: Jonathan Chew s47F @infantnutritioncouncil.com>
Cc: s47E(c), s47F @Health.gov.au>, s47E(c), s47F @Health.gov.au>, s47E(c), s47F @Health.gov.au>
Subject: RE: Request for chat - WHO EB meeting - digital marketing [SEC=OFFICIAL]

Hi Jonathon
Yes, of course
Please let me know your availability over the next few days.
s47E(c)
s47F

From: Jonathan Chew s47F @infantnutritioncouncil.com>
Sent: Tuesday, 3 December 2024 10:48 PM
To: s47E(c), s47F @Health.gov.au>
Subject: Request for chat - WHO EB meeting - digital marketing

Hi s47E(c), s47F

Would I be able to request a short call with you for some time next week to discuss the issue of the agenda item which covers the proposed resolution from Brazil about the WHO guidance on digital marketing for BMS. I would need no more than 30 mins (probably less), and happy to do it online.

Prior to the changes in the Department's personnel, I had engaged with s47E(c), s47F and Tracy on the issue, but have not discussed it with you. I am interested in know what, if any, position the Australian delegation will take on the resolution, and would like to reiterate the views of the Infant Nutrition Council about the Guidance.

Cheers
Jonathan

Jonathan Chew
Chief Executive Officer

Infant Nutrition Council

M s47F

E s47F @infantnutritioncouncil.com infantnutritioncouncil.com

s22

Subject: INC RE WHO EB Mtg - Digital Marketing [SEC=OFFICIAL]
Location: Microsoft Teams Meeting

Start: Mon 9/12/2024 11:00 AM
End: Mon 9/12/2024 11:30 AM
Show Time As: Tentative

Recurrence: (none)

Meeting Status: Not yet responded

Organizer: s47E(c), s47F
Required Attendees: Jonathan Chew

Hi Jonathon
Looking forward to speaking. In the meantime I'll ask my team to investigate where this is up to from a Department of Health perspective. It has not been on my radar – but that might be due to my having just returned from leave (I hope).
s47E(c)
s47F

Microsoft Teams Need help?

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Passcode: s22

Dial in by phone

s22 # Australia, Sydney

Find a local number

Phone conference ID: s22

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Tenant key: s22
Video ID: s22

More info

For organizers: Meeting options | Reset dial-in PIN

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Privacy and security

s22

From: s47E(c), s47F
Sent: Friday, 25 October 2024 9:48 AM
To: Jonathan Chew
Subject: Accepted: MAIF process issues [SEC=OFFICIAL]

MAIF — INC 5/4

→ MAMA s51.1 (CCA) → can legislate / regulate to exclude app'n of competition regts

eg. NR. Health Services Act 1986

must refer to exclusion

would
Need to find others

s22

From: Jonathan Chew s47F @infantnutritioncouncil.com>
Sent: Wednesday, 6 November 2024 7:01 AM
To: s47E(c), s47F
Subject: Academic Paper on Infant Formula and Emergencies
Attachments: bartick-et-al-2024-academy-of-breastfeeding-medicine-position-statement-breastfeeding-in-emergencies[52] copy.pdf

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Hi s47E(c) s47F

Just following up with a copy of that paper I mentioned yesterday.

Cheers
Jonathan

s22

From: s47E(c), s47F
Sent: Friday, 11 October 2024 12:47 PM
To: Jonathan Chew
Subject: RE: ACCC public conference [SEC=OFFICIAL]

Yes – we've let ACCC know that we will attend (we will be online). Anthea Raven (my new Assistant Secretary included). I will also attend. s47E(c) s47F might too.

From: Jonathan Chew s47F @infantnutritioncouncil.com>
Sent: Friday, October 11, 2024 12:33 PM
To: s47E(c), s47F @Health.gov.au>
Subject: ACCC public conference

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Hi s47E(c), s47F

I'm wondering if the Department of Health is planning to attend the ACCC public conference on the MAIF Agreement reauthorisation on 28 October? INC/industry will be attending, we are just confirming details/numbers now.

Cheers
Jonathan

BREASTFEEDING MEDICINE
Volume 19, Number 9, 2024
Academy of Breastfeeding
DOI: 10.1089/bfm.2024.84219.bess

ABM Emergency Statement

Academy of Breastfeeding Medicine Position Statement: Breastfeeding in Emergencies

Melissa Bartick,[1,2,*] Deena R. Zimmerman,[3] Zaharah Sulaiman,[4] Amal El Taweel,[5] Fouzia AlHreasy,[6] Lina Barska,[7] Anastasiia Fadieieva,[7] Sandra Massry,[8] Nan Dahlquist,[9] Michal Mansovsky,[10,^] and Karleen Gribble[11,^]

Abstract

Background: During emergencies, including natural disasters and armed conflict, breastfeeding is critically important. Breastfeeding provides reliable nutrition and protection against infectious diseases, without the need for clean water, feeding implements, electricity, or external supplies.
Key Information: Protection, promotion, and support of breastfeeding should be an integral part of all emergency preparedness plans. Breastfeeding specialists should be part of plan development. Emergency protocols should include breastfeeding specialists among emergency relief personnel, provide culturally sensitive environments for breastfeeding, and prioritize caregivers of infants in food/water distribution. Emergency relief personnel should be aware that dehydration and missed feedings can impact milk production, but stress alone does not. Emergency support should focus on keeping mothers and infants together and providing private and/or protected spaces for mothers to breastfeed or express milk. Emergency support should also focus on rapidly identifying mothers with breastfeeding difficulties and breastfeeding mothers and infants who are separated, so their needs can be prioritized. Breastfeeding support should be available to all women experiencing difficulties, including those needing reassurance. Nonbreastfed infants should be identified as a priority group requiring support. Relactation, wet-nursing, and donor milk should be considered for nonbreastfed infants. No donations of commercial milk formula (CMF), feeding bottles or teats, or breast pumps should be accepted in emergencies. The distribution of CMF must be highly controlled, provided only when infants cannot be breastfed and accompanied by a comprehensive package of support.
Recommendations: Protecting, promoting, and supporting breastfeeding should be included in all emergency preparedness planning and in training of personnel.

Keywords: breastfeeding, disaster preparedness, natural disasters, armed conflict, infant young child feeding

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[2]Department of Medicine, Harvard Medical School, Boston, Massachusetts, USA.
[3]Maternal Child and Adolescent Department, Public Health Division, Ministry of Health, Jerusalem, Israel.
[4]School of Medical Sciences, Universiti Sains Malaysia, Kelantan, Malaysia.
[5]Egyptian Lactation Consultants Association, Cairo, Egypt.
[6]General Administration of Nutrition, Therapeutic Services Deputyship, Ministry of Health, Riyadh, Saudi Arabia.
[7]Pershyi HVfriendly, Ukrainian Academy of Breastfeeding Medicine, Kharkiv, Ukraine.
[8]Asociación de Consultores Certificados de Lactancia Materna (ACCLAM), Mexico City, Mexico.
[9]Hillsboro Pediatric Clinic, LLC, Westside Breastfeeding Center, Retired, Hillsborough, Oregon, USA.
[10]Maccabi Health Services, Ma'alot, Israel.
[11]School of Nursing and Midwifery, Western Sydney University, Parramatta, Australia.
*Melissa Bartick, MD, MS, MPH, FABM, lead author.
^Karleen Gribble, PhD, BRurSc(Hons), CertIV BreastEd (Counseling & Community), senior author.

About ABM Position Statements: *The Academy of Breastfeeding Medicine empowers health professionals to provide safe, inclusive, patient-centered, and evidence-based care. Women and others who are pregnant and lactating identify with a broad spectrum of genders, pronouns, and terms for feeding and parenting. There are two reasons ABM's use of gender-inclusive language may be transitional or inconsistent across protocols and position statements. First, gender-inclusive language is nuanced and evolving across languages, cultures, and countries. Second, foundational research has not adequately described the experiences of gender-diverse individuals. Therefore, ABM advocates for, and will strive to use, language that is as inclusive and accurate as possible within this framework.*
For more explanation, please read ABM Position Statements on Infant Feeding and Lactation-Related Language and Gender and *Breastfeeding As a Basic Human Right.*

Introduction

During emergencies, such as natural disasters, armed conflicts, famines, and mass displacement, breastfeeding is vital to the health and well-being of infants and their mothers. Breastfeeding saves lives,[1] and this is particularly true in emergency settings. Breastfeeding provides a clean, reliable source of safe nutrition without the need for clean water, feeding implements, electricity, or other external supplies. Breastfeeding helps to prevent infections and malnutrition, both of which can be a significant risk in emergency situations.[2] In addition, breastfeeding reduces the maternal stress response,[3] partly through the release of the hormone oxytocin,[4] which helps increase maternal resilience in the face of traumatic circumstances.[5,6] A reduced stress response helps mothers provide sensitive, loving care to their infants, thereby protecting the mental health and development of children.[7] Breastfeeding (even the odor of breast milk[8]) is known to decrease infants' stress and pain responses,[9] which is helpful during a crisis. Breastfeeding also protects maternal health during emergencies related to birth spacing and preventing excessive postpartum hemorrhage.[10]

In contrast, the emergency milieu increases the risks associated with feeding of commercial milk formula (CMF). Feeding implements (including cups, bottles, and teats) require washing with hot water and detergent and powdered infant formula requires boiled water for reconstitution. These resources are often scarce in emergencies. Infants who are dependent on CMF are vulnerable to food insecurity due to supply chain disruptions that commonly occur in emergencies. They are also deprived of the many ingredients in breast milk that protect against infection, whereas infant formula itself affects the gastrointestinal environment in a way that facilitates infection.[11]

Severe weather and natural disasters are becoming increasingly common with climate change.[12] Children are disproportionately impacted by climate change.[13] In addition, in 2022, more than two-thirds of the world's children were living in countries experiencing conflict, and 1 in 6 children were living less than 50 km from where fighting was taking place.[14] In light of the contribution of breastfeeding to infant health, well-being, and survival, as well as to maternal health, health care professionals as well as emergency relief personnel should act to support breastfeeding mothers in emergency situations and ensure appropriate targeted support for nonbreastfed infants and their caregivers.

The ABM Position Statements Breastfeeding as a Basic Human Right[15] and Informal Breast Milk Sharing for the Term Healthy Infant,[16] and the ABM Protocol #35 Supporting Breastfeeding During Maternal or Child Hospitalization,[17] serve as important adjuncts to this Position Statement. In addition, all ABM protocols that help promote breastfeeding, such as #37 Physiological Infant Care,[18] #2 Guidelines for Birth Hospitalization Discharge,[19] and #14 Breastfeeding Friendly Physician's Office[20] also serve as important resources.

Recommendations

The Academy of Breastfeeding Medicine makes the following recommendations, based not only on international guidelines but also on our synthesis of available information and on expert opinion.

Protection, promotion, and support of breastfeeding should be enabled at all times

The more women who are breastfeeding before the disaster, the more breastfeeding women there will be able to continue at times of emergency. At an individual level, breastfeeding should be promoted as an emergency preparedness action and women should be encouraged to factor emergencies into their infant feeding decisions. Exclusive expressing of breast milk without a medical reason should be discouraged. Women who exclusively use breast pumps should be referred for help to transition to direct breastfeeding and should know how to hand express. Governments should be encouraged to consider high breastfeeding rates as supporting community resilience to emergencies and view investment in breastfeeding support as emergency preparedness. As a part of this, implementation of the Baby-Friendly Hospital Initiative (BFHI) should be supported.

Emergency plans should include skilled breastfeeding support and breastfeeding specialists

Trained personnel should be available to support and assist breastfeeding mothers with issues that arise as a result of the emergency, including those related to ordinary breastfeeding concerns, issues requiring reassurance, low milk production, relactation, facilitation of wet nursing, assistance of mothers who are separated from their infants, and assistance for those who are exclusively expressing breast milk. Breastfeeding specialists should be trained on how to counsel and assist breastfeeding mothers who request CMF.

Ensure training of emergency relief personnel so that they are able to support breastfeeding dyads within their role

Emergency relief workers should receive basic training and sensitization on the support needs of breastfeeding women in emergencies and on Infant and Young Child Feeding in Emergencies (IYCF-E) policies and procedures. Educational messages should include breastfeeding is the safest and most reliable source of infant nutrition during an emergency. Training should include content on the harm of providing CMF to breastfeeding mothers and where to refer breastfeeding mothers or other caregivers who request formula.

In cases of mother–infant separation, wet-nursing (breastfeeding from another mother) or use of donor milk should be considered

Health screening of wet nurses and milk donors should be informed by available resources (e.g., testing for infectious diseases) and local prevalence of infections of concern. Breast milk donation should be done through local milk banks. Milk banks should be included in emergency planning and have their own emergency plans. Local informal milk sharing may be necessary if use of banked milk is not available.

In cases of mother–infant separation, assure maternal milk production

Mothers who are separated from their infants should be encouraged and supported to hand express their milk. Breast pumps should only be considered for use if abundant hot water for washing is available. Separated mothers may be willing to wet-nurse infants in need of breast milk.

Emergency plans should include provisions that support breastfeeding in shelters and mother–baby areas

Planning should include breastfeeding support in emergency shelters. Emergency shelter protocols should enable staff to rapidly identify the feeding needs of each family with infants and young children, as well as breastfeeding mothers and infants who are separated.

Women should be able to access breastfeeding support on-site or facilitated to access support off-site, including via electronic communication or telephone. Breastfeeding mothers and the other caregivers of infants and young children should receive priority in queuing for food and water distribution. Emergency shelters should include a protected space for mothers to breastfeed their children or express their milk with the amount of privacy the mother requires according to local cultural practice.

Mother–baby areas (MBAs) to facilitate maternal psychological well-being, breastfeeding, and other health support should be set up during emergencies and in their aftermath.

Infants not directly breastfed should be fed using a cup if there is no reliable source of clean water

Use of bottles and teats for feeding infants should be strongly discouraged in circumstances where adequate washing with hot water is not possible. In these situations, cup feeding, including with disposable cups, should be supported. Similarly, use of breast pumps should also be strongly discouraged where adequate washing with hot water is not possible, and instead hand expression should be supported.

Nonbreastfed infants should be considered a vulnerable group and appropriately supported, with use of breastfeeding or donor milk as initial options

CMF should only be provided after an assessment of need by appropriately trained health providers. Breast milk options for feeding nonbreastfed infants should be explored first as follows: relactation, wet-nursing, and donor milk (in that order) and if these are not available, CMF. If a decision is made to provide commercial milk to an infant, it must be accompanied by guidance on safe preparation under the emergency conditions and caregivers must be ensured access to other resources needed to feed with an adequate level of safety. These resources include the following: clean water for reconstitution and washing, an ability to heat water for reconstitution and washing, and adequate feeding implements as well as health monitoring and health care, with a commitment to provide this support for as long as the infant needs it.

The international code for the marketing of breastfeeding substitutes should be followed, and guidance on donations and distribution from the Infant and Young Child Feeding in Emergencies-Operational Guidance should be followed

Donations of CMF, other breast milk substitutes, bottles and teats, commercial complementary foods, and breast pumps should not be sought or accepted, but rather should be publicly discouraged. CMF distribution must be strictly controlled by emergency relief personnel, provided only when an infant cannot be breastfed, and should not be routinely distributed. CMF should not be distributed to exclusively breastfeeding mothers. CMF should be stored and distributed discreetly so as not to discourage breastfeeding mothers. Advertising and sponsorship related to CMF and other breast milk substitutes, bottles and teats, and breast pumps should not be permitted in emergency shelters or in any other aspect of emergency response (e.g., on or inside care packages).

Feeding complementary foods or liquids to infants younger than 6 months should be discouraged and infants younger than 6 months should not be provided with solid food

Complementary feeding of infants 6–23 months should be supported in emergency response. Any complementary foods that are provided should be safe and appropriate, and donations of commercial complementary foods should not be solicited or accepted.

Key Information to Support Recommendations

Background

Natural and human-origin disasters can cause destruction and widespread disruption, including to breastfeeding mothers and their breastfed children and to nonbreastfed infants and their mothers and caregivers, leading to the need for an emergency response.

The *Global Strategy for Infant and Young Children Feeding* from the World Health Organization and UNICEF recommends exclusive breastfeeding for the first 6 months of life, after which appropriate complementary foods should be introduced with breastfeeding continuing alongside for up to 2 years or beyond.[21] Infants younger than 6 months should not be fed liquids other than breast milk or CMF, including teas, juices, or homemade formulas.[21,22]

The main internationally recognized core guidance resource for infant and young child feeding is the *Infant and Young Child Feeding: Operational Guidance for Program Managers* (OG-IFE), which provides detailed guidance on emergency response to meet the feeding needs of infants and young children.[23] In 2010, the World Health Assembly urged all member states to ensure that they had national emergency preparedness plans in line with the OG-IFE.[24] A second influential resource is *The Sphere Handbook: Humanitarian Charter and Minimum Standards in Disaster Response* (Sphere Handbook), which provides direction on aid provision across the breadth of human needs in disasters.[25] The *Sphere Handbook* adapts and reflects the OG-IFE, and provides minimum humanitarian standards. The recommendations made in this Position Statement are informed by the OG-IFE and therefore are also aligned with the Sphere Handbook. Additional resources to support IYCF-E response can be found in Table 1. This Position Statement also draws from many resources and presents a compilation and synthesis of information that will be useful for those preparing for emergencies or working in an emergency situation.

Personnel who provide support during an emergency to breastfeeding mothers and other caregivers of infants and young children may include government employees, nongovernmental organizational staff, volunteers, and health care providers. In this document, we refer to them broadly as emergency relief personnel or aid workers.

Population feeding practices and beliefs

Population infant and young child feeding practices before the emergency greatly impact the required emergency response.[23] Populations with a strong breastfeeding culture, high rates of early, exclusive, and continued breastfeeding, and robust community and health system support of breastfeeding will be more resilient in emergencies. In such circumstances, emergency response will be able to focus almost entirely on supporting women to breastfeed with only small numbers of nonbreastfed infants requiring assistance. However, many low- and middle-income countries (LMICs) have high rates of any breastfeeding but may also have high rates of prelacteal feeding and mixed feeding, with breastfed infants also being fed with animal milk, cereals, or CMF. The IYCF-E response in these circumstances is more complex and challenging, with a need to support women not just to continue breastfeeding but to cease mixed feeding and exclusively breastfeed if possible.

In addition, in some high-income countries, a significant proportion of infants may be not breastfed (fully dependent on CMF). An IYCF-E response in communities with a large proportion of infants who are not breastfeeding at all is

Table 1. Online Resources for Infant and Young Child Feeding in Emergencies

Resources for global usage
IFE-Core Group resources, including the OG-IFE; the guidance on *Chemical, Biological, Radiological and Nuclear Threats Guidance*; *Operational Guidance: Breastfeeding Counseling in Emergencies*; the IYCF-E Research Repository; and the IFE Core Group infographic series (early initiation of breastfeeding in emergencies, preventing inappropriate donations of commercial milk formula, planning and managing artificial nutrition during emergencies, supporting infants who are dependent on CMF, infant feeding decisions during infectious disease outbreaks) https://www.ennonline.net/network/ife-core-group
EN-net online forum has an IYCF-E forum where questions can be asked and answered in both English and French. https://www.en-net.org/
World Health Organization's relactation resource (not specific for humanitarian contexts) *Relactation: Review of experience and recommendations for practice* (1998) https://www.who.int/publications/i/item/WHO-CHS-CAH-98.14
Global and country resources for humanitarian contexts
IYCF-E Hub by Save the Children includes a vast number of IYCF-E resources, including those related to breastfeeding, supporting nonbreastfed infants, and complementary feeding in many different languages, emergency types, and country contexts. https://iycfehub.org/
Resources for high-income country usage
U.S. Centers for Disease Control and Prevention IYCF-E Toolkit including emergency preparedness, breastfeeding and CMF feeding resources, social media tiles, emergency shelter signage, fact sheets for emergency shelters, rapid needs assessment guide. https://www.cdc.gov/infant-feeding-emergencies-toolkit
Australian Breastfeeding Association resources including evacuation kit lists for infants and young children and emergency planning tools for parents, fact sheets for mothers and caregivers on IYCF-E (breastfeeding, expressed breast milk feeding, and formula feeding in emergencies, cup feeding and hand expressing, emergency shelter exercise scenarios for IYCF-E, free e-learning module for emergency relief personnel on support families if infants and young children. https://www.breastfeeding.asn.au/emergency-resources-babies-and-toddlers

Care should be taken to ensure that resources are suitable for the setting in which they will be used.

CMF, commercial milk formula; IFE, infant feeding in emergencies: OG-IFE, Infant and Young Child Feeding in Emergencies-Operational Guidance; IYCF-E, Infant and Young Child Feeding in Emergencies.

extremely challenging because of the vulnerability of these infants and the resources required to support their feeding needs. Finally, some countries have mothers who do not directly breastfeed their infants but instead exclusively express their milk with breast pumps and bottle feed their infants. As discussed later, these mothers and infants have particular support needs.

Different countries and communities not only have different feeding practices but broader differences in customs, religious beliefs, and in resources that impact health care availability, infant feeding, and infant mortality in general. They also have differences in emergency planning, emergency response practices, and capacities, including the involvement or not of humanitarian actors. All of these factors should be taken into consideration in supporting infant and young child feeding in emergencies and in applying the recommendations made in this Position Statement.

Breastfeeding in the Context of IYCF-E

Supporting breastfeeding in emergencies

Even though emergencies enhance the importance of breastfeeding, challenges associated with emergency conditions can make it difficult for women to breastfeed. The OG-IFE and Sphere Handbook both emphasize the need for breastfeeding women to receive skilled breastfeeding counseling in emergencies.[23,25] Depending on the country and its resources, this support can include a variety of personnel, including nutritionists, medical doctors, International Board-Certified Lactation Consultants, persons with certifications in breastfeeding counseling or education, and volunteer breastfeeding counselors such as La Leche League Leaders. The Emergency Nutrition Network and the IFE Core Group has also published *Operational Guidance: Breastfeeding Counseling in Emergencies* to assist in the planning and implementation of breastfeeding counseling in emergencies.[26]

One of the most common problems those supporting breastfeeding in emergencies will encounter is women who believe that stress has reduced their milk production. This concern is consistently reported irrespective of country or emergency type and can have the result of women introducing other foods and liquids or stopping breastfeeding. During conflict in Ukraine in 2015, stress was the most common reason given by women for ceasing breastfeeding and almost half of mothers who stopped breastfeeding their infants younger than 6 months named the stress of the conflict as the reason.[27] Health workers may also believe that stress adversely impacts breastfeeding as was found among those providing nutritional support to malnourished infants in an internally displaced persons camp in northern Nigeria,[28] thus compromising their ability to assist. Very often women who believe that stress has reduced their milk production base this belief upon observed infant behavior changes such as wanting to feed more frequently, being unsettled during feeds, and waking more often overnight. However, these behavior changes are normal in the context of the disruption of an emergency.[29] Stress results in decreased frequency of pulsatile releases of the hormone oxytocin, thus slowing the release of milk (letdown), which means feeds may take longer.[30] This effect on oxytocin does not affect the overall milk production in the short term, but over the longer term, chronic impairment of letdown might conceivably result in less effective milk removal, thus potentially impairing production.[31] Changes in letdown can contribute to infant fussiness. Stress may also cause women to be less responsive to infant hunger cues,[32] and thus feed them less frequently, which will also result in decreased milk production. In general, issues with actual or perceived decreased milk production are more likely to be the result of decreased feeding frequency and dehydration than directly as a result of stress itself. It is also common for women to believe that lack of food or not having access to particular foods will impact the quantity or quality of their milk.[33] Breastfeeding counseling and psychological and other supports can assist women who lack confidence in their ability to breastfeed to continue to breastfeed.[34]

A variety of cultural beliefs can impact breastfeeding practices. Mothers may need to be reassured regarding a belief that negative emotions may impact the quality of their milk,[35] or that supernatural forces affect their breast milk.[36] Women may also have concerns that breastfeeding is dangerous due to experiences, such as being ill with diarrhea or other foodborne illness,[37] or because they are stressed or traumatized.[33] In the vast majority of circumstances, with information and reassurance, women are able to continue breastfeeding.[17,38]

Dehydration, reduced feeding frequency (due to constant movement, busyness, exhaustion, or lack of privacy),[39] or ordinary breastfeeding problems such as poor positioning and latch[28] may diminish milk production. Mothers can be reassured that milk production can be quickly increased with proper hydration, increased feeding frequency, and improved positioning and attachment. As discussed later, practical supports should be implemented to address the underlying reasons for dehydration or infrequent feeding and to otherwise support breastfeeding women. Mothers who are not exclusively breastfeeding their infants younger than 6 months should be sensitively encouraged to transition their infants to full breastfeeding.[23,25] Supplementary feeding until exclusive breastfeeding is achieved is discussed later. Women may also experience breastfeeding difficulties such as mastitis, hyperlactation, or nipple pain and injury and require assistance.

In some cases, health care workers and other aid workers have provided breastfeeding women with poor information, advice, or support such as telling them to stop breastfeeding if they have a minor illness, if their infant cries, and in some cases, they simply encouraged mothers to give their infant CMF.[39] Some women, weakened by the stress of the emergency, have felt coerced into giving CMF, even by medical staff.[40] This underlies the importance of ensuring that health staff and others are oriented to key breastfeeding information and IYCF-E principles and know the referral pathways for breastfeeding women experiencing difficulties.[41]

Assisting breastfeeding mothers in special circumstances

Mothers mix-feeding infants younger than 6 months should be sensitively encouraged to transition their infants to exclusive breastfeeding if possible.[23,25] These mothers should be encouraged to breastfeed their infants frequently to increase milk production and infant breast milk intake.[42] Skilled breastfeeding support will likely be necessary.

Infants will require some supplementation with donated milk, wet-nursing, or CMF until mothers can exclusively breastfeed.

It is vital that breastfeeding mothers who are separated from their infants begin to express their milk frequently or, if appropriate, wet-nurse other infants to maintain their own milk production. Milk expression (or wet-nursing) should begin as soon as possible after separation from their infant. If they express their milk, this milk may be available to nearby infants for informal milk sharing, if that is appropriate given the circumstances. Skilled breastfeeding and emotional support would be very helpful to these mothers.

Mothers who exclusively express milk to feed their infants have particular challenges during an emergency. They may have been accustomed to using breast pumps to express their milk and bottles to feed their infants, both of which require abundant hot water for effective washing. They may also need a power source if they use an electric pump. Their infant may or may not have experience with direct breastfeeding and may thus be unfamiliar with how to breastfeed effectively or be reluctant to do so. In addition, such mothers may depend on caches of their milk stored in a refrigerator or freezer, which may be compromised in a power outage, and they also may not have access to their stores of milk if they are evacuated from their homes. In recognition of the difficulty of washing breast pumps effectively, the OG-IFE states that use of breast pumps "should only be considered if their use is vital and where they can be cleaned, as in a clinical setting." (page 13)[23] Mothers who have been exclusively expressing should be encouraged to transition their infants to direct breastfeeding if possible and provided with skilled support to do so. If they are unable or unwilling to make this transition, women who are exclusively expressing should be taught how to hand express and cup feed their infants. *Cup feeding* is discussed in a later subsection in relation to CMF feeding.

In circumstances in which either the breastfeeding mother or the infant or young child is hospitalized with injuries, keeping mothers and infants together and supporting breastfeeding can be crucial to their recovery, and emergency protocols should address this possible scenario. Breastfeeding can help stabilize the vital signs of mothers and infants.[17] For mothers, the presence of her infant can help her recovery and provide her with a stronger will to recover.[17] Refer to ABM Protocol #35, Supporting Breastfeeding During Maternal or Child Hospitalization.[17]

It is important to ensure safety and support to families who have vulnerabilities related to domestic violence, disability or medical conditions, religious or cultural needs, marginalization or other special needs.

Relactation, wet-nursing, and donor milk for nonbreastfed infants

For infants younger than 6 months who are not breastfed, the OG-IFE calls for relactation, wet-nursing, or donor milk, in that order. Only if all these options are not acceptable or feasible is support for CMF feeding for infants younger than 6 months old appropriate.[23] The IFE Core Group has produced an infographic summary on how to support nonbreastfed infants in emergencies to guide policy development and individual action.[43]

Relactation is a process in which a woman who has given birth and stopped breastfeeding this infant or breastfed a previous infant is stimulated to restart lactation. (All women initially lactate after birth, although not all breastfeed.) Induced lactation refers to a process in which a woman who has never given birth is stimulated to lactate.[44] Relactation may be undertaken by the mother of the infant, or if she is not available, relactation or induced lactation may be undertaken by a family member such as an aunt or grandmother, who may volunteer to wet-nurse the infant. Women who are strongly motivated to relactate will be more likely to be successful than those who are less strongly motivated.[45] Women are also more likely to be successful in relactation if those supporting them are confident in relactation as a process.[46] Guidance for health providers on supporting relactation is available from the World Health Organization in its publication *Relactation*.[44] A systematic review of relactation, which included a humanitarian setting, found that the start of milk secretion varied from 2 to 15 days, mixed feeding was achieved between 2 and 18 days, and exclusive breastfeeding could be achieved from 3 to 30 days.[47] Mothers who had most recently stopped breastfeeding and who were not using bottles had greater success, and mothers do better with more intensive support, particularly in the first 10 days.[47] Equipment for supplementation while suckling at the breast, including supply tubing (also called a breastfeeding supplementer or supplemental breastfeeding system), may be used where hot water for washing is available such as in a clinic setting.[48] Women who have recently stopped breastfeeding any child younger than 6 months should be counseled to consider relactation, although relactation can be tried for infants and children who are older as well.[49] Skilled breastfeeding support is very important for these mothers,[23,47] although relactation in emergencies has been successfully supported by health workers with limited experience.[50]

After relactation, wet-nursing is the next feeding option to consider in emergencies, both for infants who are not breastfed and for separated mothers and infants. Wet-nursing, the practice of family and community members breastfeeding an infant that is not their own, has long been a part of infant feeding in many societies through much of human history. It can be considered if it is acceptable to the mother and the family of the infant and a suitable wet nurse can be identified.[2,23,51] It is important to note that while wet-nursing may not be culturally acceptable in some settings, emergencies can change perceptions.[52] Recent experiences during the Ukraine war saw wet-nursing serving as a lifeline for infants trapped under siege, where sometimes individual mothers fed multiple infants.[53] It is therefore important not to prejudge whether an infant's family will consider wet-nursing.[52] Close relatives (such as sisters, aunts, and grandmothers) or friends are more likely to be acceptable as a wet nurse than someone unknown to the family.[52] However, wet-nursing by strangers, including emergency responders (who may undertake this role on a short-term basis), also occurs during emergencies.[54] The legal and regulatory framework for wet-nursing and donor milk use, particularly in emergencies, may vary from country to country or may be absent.[51]

Wet-nursing can also help a mother maintain her milk production if she is separated from her own infant. Prospective

wet nurses should undergo HIV counseling and rapid testing if it is feasible, and if it is not feasible, they should undergo an HIV risk assessment.[23] Wet nurses should be appropriately supported in this important work, which may include provision of resources, but care should be taken to ensure that women are not coerced by family members or otherwise to wet-nurse.[52] Refer to OG-IFE and the Operational Guidance: Breastfeeding Counseling in Emergencies for more information regarding HIV.[23,26]

Donor milk should ideally come from milk banks, where it is pasteurized and where donors have been screened. Some countries have robust milk banking systems, which makes this a possibility. For example, banked milk has been provided to emergency shelters for use to feed nonbreastfed infants in some emergencies in the Philippines.[55] However, not every country has such capacity. Donor milk from milk banks requires a cold chain, logistical support, and a strong management system.[23,51] Power outages and transportation issues may pose significant logistical challenges to using banked milk, even where it exists. In addition to infrastructure challenges during a disaster, excessive attention to donated milk risks diverting attention away from breastfeeding support.[51] International donations of banked donor milk should not be made.[23] When donor milk is in short supply, it should be prioritized for low birthweight infants, premature, and sick infants.[23] Milk banks should develop emergency preparedness plans, which include how to stockpile supplies for an emergency, developing criteria and logistics for distribution of milk during an emergency, and how to solicit milk and monetary donations during an emergency.

Milk may be shared directly from one mother to another mother or caregiver during emergencies. The OG-IFE notes that there is little experience with informal milk sharing in this setting.[23] However, a recent report from Ukraine described the sharing of expressed breast milk during conflict.[53] ABM has a Position Statement on Informal Milk Sharing (2017), but it is not specific for disaster situations, and it calls for prospective recipients to screen the donor for use of medications compatible with breastfeeding, tobacco products, use of substances that are not compatible with breastfeeding (such as cocaine), and infections such as HIV, and HTLV-1 (in endemic areas).[16] This guidance contrasts with the OG-IFE, which only recommends testing or screening for HIV[23] and screening for HIV would be the most important consideration for informal milk sharing in an emergency situation.

The issue of milk kinship should be considered with wet-nursing or milk sharing among Muslim families.[56] Although it is sometimes believed that Islamic milk kinship precludes wet-nursing or milk sharing, this is not the case. In fact, there is a strong history of wet-nursing in Muslim cultures and identification and documentation of the donor or wet nurse will often be enough to address any concerns related to milk kinship.[52] Involvement of trusted religious leaders can also facilitate the acceptance of wet-nursing.[52]

The capacity of wet-nursing and milk sharing to support the health and well-being of nonbreastfed infants points to the contribution of high breastfeeding rates to community resilience in disasters. Government investment in supporting breastfeeding should be considered an essential emergency preparedness activity as having more breastfeeding women in a community can be lifesaving for all infants (breastfed and nonbreastfed).[53] All emergency plans and policies should include breastfeeding support.

Minimizing the risk of artificial feeding with CMF

Infants younger than 6 months for whom breastfeeding or the provision of breast milk is not possible should be supported in CMF feeding. Nonbreastfed infants who are older than 6 months can be fed with animal milk, CMF (only up to 12 months), plus appropriate complementary solid foods.[57] CMF is not recommended for children older than 12 months.[57] Note that feeding with animal milk might increase the risk of iron deficiency,[57] so ensuring iron-rich complementary foods is of increased importance for such infants and supplementation with iron may be necessary if these milks are used. A decision to provide CMF to infants who cannot be breastfed entails a significant commitment. It is much more costly to support CMF feeding than breastfeeding, especially in a humanitarian crisis.[58] Organizations that distribute CMF in emergencies are required to provide it for as long as the child needs and to ensure that all resources necessary to feed CMF with an acceptable level of safety are available to the caregiver.[23,25] These resources include clean water for reconstitution and washing, an ability to heat water for reconstitution and washing, and feeding implements, as well as individualized education and health monitoring and health care. CMF should not be distributed without individual assessment of need by a suitably qualified person.[23,25] Emergencies bring elevated rates of infant morbidity and mortality, particularly for infants who are not breastfed or not exclusively breastfed,[59 61] which is the primary reason why supply of CMF should be tightly controlled and must be accompanied by a comprehensive package of support.

Temporary provision of CMF is indicated for those infants younger than 6 months whose mothers (or caregivers) are relactating, who are transitioning from mixed feeding to exclusive breastfeeding, those enduring short-term maternal separation, or awaiting donor milk or wet-nursing.[23] Longer term CMF is appropriate for infants until 6 months who were dependent on CMF pre-emergency, whose mothers cannot or are unwilling to relactate for whatever reason, or for whom donor milk or wet-nursing is not an option, for whatever reason. Other indications, as outlined in the OG-IFE, include orphaned infants, infants whose mothers are absent long term, infants of mothers with recognized medical conditions in which breastfeeding is contraindicated, a very ill mother unable to breastfeed, an infant rejected by the mother, and a sexual assault survivor not wishing to breastfeed.[23] Maternal desire to formula feed without one of these reasons is not an indication for CMF provision, and CMF provision should be avoided absent one of the above reasons.

The OG-IFE, *Sphere Handbook* and the WHO International Code of Marketing of Breast-Milk Substitutes (the Code) specify that CMF for infants who cannot be breastfed must be purchased rather than donated, as experience has shown that donated CMF is often improperly distributed.[23,25,62,63] For example, after the Yogyakarta, Indonesia earthquake in 2006, three-quarters of households with an infant 0–5 months received donated infant formula[59] despite high levels of breastfeeding before the emergency. (See subsection *Donations of CMF and other infant feeding products* for more information on donations of CMF.)

Any CMF provided by emergency relief personnel to caregivers should be purchased rather than donated.[23,25] In humanitarian contexts, UNICEF is the agency through which CMF should be procured, and it has a procurement guide for this process.[64] There are a number of factors to consider when purchasing CMF for use in an emergency. For a variety of reasons, infant formula (commonly called "stage 1") should be purchased for use in any CMF program, including for feeding of infants 6–12 months.[65]

Liquid ready-to-use infant formula (RUIF) has the advantage of not requiring reconstitution and is sterile, but it is also expensive, bulky, and heavy and so can be difficult to store and transport. Because it is sterile, RUIF may be erroneously perceived as not having any risks associated with its use, which may lead to overuse. RUIF is also not available in all locations, may only be available in large volumes (e.g., 450 mL sizes), and may not be acceptable to caregivers unaccustomed to this form of CMF. Where RUIF is used, it should be purchased in small serving sizes with caregivers educated on the need to discard excess milk following feedings.[65] Powdered infant formula (PIF) requires clean water for reconstitution and it is also recommended that hot water be used for reconstitution to kill pathogens that may be present in the powder.[66] The WHO recommends water (including bottled water) be brought to a rolling boil and allowed to cool to no less than 70°C/130 °F (waiting 5 minutes, e.g., but the WHO specifies no more than 30 minutes), before PIF is added.[66] After mixing water with PIF, the reconstituted CMF should be quickly cooled by running it under cold water or putting into ice, and it should be checked to make sure it is cooled to a temperature safe for consumption.[66] However, this can be extremely difficult to do in emergencies. Concentrated liquid formula is not recommended for use in emergencies due to potential errors in dilution.[23] CMF should be labeled with instructions in the language understood by those using it. As previously noted, when infant formula is provided, individualized education on use should also be given. For further information on infant formula procurement in emergencies, see Gribble and Fernandes (2018)[65] and the OG-IFE guidelines.[23]

Figure 1 illustrates the feeding options in order of priority for infants younger than 6 months during emergencies.

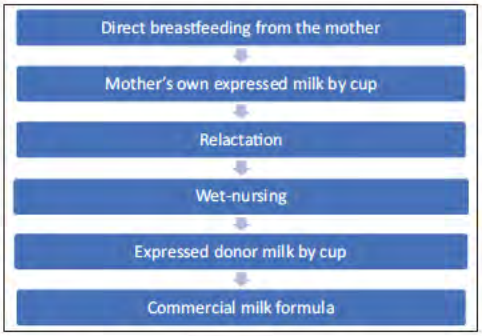

FIG. 1. Feeding options in order of priority for infants younger than 6 months in emergencies. Note: In instances in which any of these resources conflict with the *Infant Feeding in Emergencies: Operational Guidance (OG-IFE)*, the OG-IFE guidance should be followed.

Cup feeding

Caregivers of infants who are being fed expressed breast milk or CMF should be encouraged to use cups rather than bottles and teats to feed their infants in any circumstance where liberal hot water for washing is unavailable.[23] This is because cups can be properly cleaned more easily and thoroughly than bottles and teats. Even newborn infants can feed with a cup, and guidance is available on how to support caregivers with cup feeding.[67] Small cups where fingers can easily reach to the bottom when cleaning (and without a spout) are best. Small disposable plastic or paper cups avoid the need for washing and can also be used. Cups with lids might be necessary for caregivers who are traveling. If caregivers are unwilling to use cups, risk mitigation strategies should be put in place where possible, for example, sterilization facilities on-site (in addition to washing sites) and provision of instructions on how to sterilize at home.[23]

Donations of CMF and other infant feeding products

Donation and inappropriate distribution of CMF and other breast milk substitutes are a pervasive problem globally, and extensive evidence shows that donations increase use of CMF by breastfeeding mothers in emergencies and undermine appropriate support for nonbreastfed infants.[35,41,53,59,65,68 71] Donations of CMF are commonly far in excess of that required, in the wrong place, of the wrong type, and close to or past expiry.[65] Donations are difficult for emergency relief workers to manage and are often distributed indiscriminately, including to breastfeeding women. For a variety of reasons, the presence and distribution of donations commonly result in women terminating exclusive or any breastfeeding.[59,68 70] After the Yogyakarta earthquake in Indonesia in 2006, nonscreened distributions of CMF saw infants (0–5 months) whose households were provided with donated CMF being 60% more likely to have been fed CMF in the previous 24 hours and more than twice as likely to have had diarrhea in the last week than infants whose households had not received donated CMF.[59] Donations also undermine the well-being of infants who cannot be breastfed as distribution is rarely accompanied by the supplies and support needed for use with an acceptable level of safety.[65]

Donations may be made by well-meaning members of the public, governments, nongovernmental organizations, or businesses (encouraged by media reporting),[65,72] or made by CMF manufacturers as a way of promoting their products.[73] Donations made in emergencies by the CMF industry are a part of a pattern of exploitative marketing to undermine breastfeeding and encourage the unnecessary and harmful use of their products.[74,75] Donation of CMF and other breast milk substitutes in emergencies is in breach of the Code.[63] The OG-IFE and the *Sphere Handbook* expressly prohibit accepting and soliciting donations of CMF and urge action to prevent donations.[23,25] A scoping review of high- and middle-income countries found that violation of the Code was widespread and problematic, including acceptance of CMF donations and lack of knowledge of the Code by aid workers who often were unwilling to follow OG-IFE protocol.[39]

Any donations of CMF that are made should be collected and disposed of; options for disposal include feeding to animals, or mixing with a cereal to be used as a complementary

food.[23] However, it should be recognized that throwing out or destroying donated CMF is often difficult to do, even in high-income countries. For example, donations of expired CMF made after the 2011 Christchurch earthquake remained in health facilities for months.[76] Prevention of donations through policy and prompt media communications are therefore critically important. If breastfeeding women have already received donated CMF or other milk, they should be advised to use it only to prepare food for children older than 6 months or to drink it themselves.

Donations of commercial complementary foods should not be solicited, accepted, or distributed.[23] Problems underlying guidance to reject donations of commercial complementary foods include the following: nutritional poverty, labeling in breach of the Code (including suitability for infants younger than 6 months), commercial exploitation of emergencies, displacement of local foods, excessive and discontinuous supply, and time-resourcing requirements to manage donations.[77]

Donations of any form of breast milk substitutes (e.g., baby teas and juices and toddler milks), bottles and teats, and breast pumps should not be accepted.[23] The IFE Core Group has produced an infographic to guide preventing and managing inappropriate donations.[78]

Purchasing and distributing CMF so that breastfeeding is protected

Where CMF is purchased, distribution is more carefully managed as it must be budgeted and accounted for. This has been shown in nonemergency settings in hospitals.[79]

Ensuring that CMF is distributed only in cases of genuine need in line with the OG-IFE is challenging, particularly where breastfeeding women have requested CMF, which is a common situation. Maternal requests for CMF are often related to the previously described belief that stress reduces milk production or other concerns related to breastfeeding inability. Additional underlying issues may be related to normalization of CMF feeding within the culture creating an expectation to formula feed, an aspiration to formula feed, or simply that CMF is a high-value product. The impact of preemergency exploitative marketing of CMF should also be appreciated such as the case of the Syrian refugee mother described by Palmquist and Gribble who was concerned that not feeding CMF would be detrimental to her infant's immune system.[80] Research on experiences regarding CMF distribution during the European Refugee Crisis of 2015-16 identified that good practice in distribution of CMF was facilitated by the following: the presence of breastfeeding support, presence of properly implemented CMF programs, understanding maternal choice to formula feed should be considered within the risk context of the emergency, consideration of CMF as more similar to a medicine than a food in emergencies, and positive personal breastfeeding experiences of emergency relief personnel.[41]

Any CMF should be kept out of public view, and distributed discreetly so as not to discourage breastfeeding mothers.[23] Using a system to identify those caregivers/mothers who truly need this product can be helpful. In the Za'atari refugee camp in Jordan, a system of prescription was developed that ensured that CMF was distributed only to those needing it and accompanied by appropriate support.[81] Among the benefits of this system was that the selling of excess CMF in the camp ceased. In addition, consideration should be given to providing breastfeeding women with something of a similar value to goods provided to CMF caregivers (e.g., additional food rations, a breastfeeding shawl, or a cooking pot) so as not to discourage breastfeeding.[65]

Given the importance of preventing donations of CMF and the exploitation of emergencies by CMF manufacturers, all health care professionals should be familiar with the Code and support national efforts to implement the Code and the subsequent World Health Assembly resolutions.[39,63] Practical advice on how to accomplish this can be found in the World Health Organization's *Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children*.[82]

Complementary Feeding in Emergencies

Complementary foods (solids) should not be fed or provided to infants younger than 6 months, as this may contribute to making infants vulnerable to infectious disease and malnutrition.[57] Complementary foods for infants older than 6 months should be of the appropriate amount, consistency, variety, and nutritional quality.[57] They should also be acceptable to caregivers.

Supporting Breastfeeding Mothers and Caregivers of Infants in Emergency Shelters

In many contexts, emergency shelters are set up to provide temporary refuge and resources to emergency-affected populations. Such venues may be in existing buildings or may be in temporary structures such as portable buildings or tents. Depending on the emergency, the longevity of such shelters may be as short as several hours or days or weeks to months. Some people may use emergency shelters to access resources but not sleep there. Emergency shelters are an important venue for provision of breastfeeding and infant feeding support.

Those caring for infants should be identified upon entering shelters to determine their immediate and medium-term needs. This may be facilitated through a registration process. Those who may require immediate assistance include the following: women experiencing difficulties breastfeeding, breastfeeding infants and mothers who are separated from one another, women who are exclusively dependent on breast pumps for providing breast milk for their infants, infants younger than 6 months who are not currently breastfed, mothers with infants younger than 6 months who mix feed (i.e., partially dependent on CMF), and orphaned infants and young children. A recent comprehensive review of ICYF-E by Bilgin and Karabayir has a helpful intake form that can be used in the registration process.[83]

Ideally, health providers with skills in IYCF-E, including those trained in breastfeeding support, should be available on-site to assist mothers and caregivers with infant and young child feeding-related needs. Otherwise, off-site support, including via telephone, should be made available. Lack of privacy in emergencies has often been identified as a barrier to breastfeeding and can reduce feeding frequency resulting in reduced milk production.[39,69,72] Therefore,

venues of evacuation or shelter should have private spaces in which women can breastfeed their children, with the amount of privacy that the mother requires according to local cultural practice.

It should be ensured that caregivers of CMF-dependent infants, or those providing CMF temporarily while relactating or otherwise awaiting resumption of breastfeeding, have a clean space within shelters to prepare feeds, and, if possible, to wash feeding implements. Emergency relief personnel should be proactive in ensuring that CMF is not prepared or feeding implements washed in the bathroom/toilet facilities to minimize the risk of fecal–oral contamination of infant food. Where appropriate facilities for washing, including hot water, are not available, single-use feeding implements should be available.

Caregivers of all infants should be prioritized for access to resources, including food and water, so they do not need to stand in long queues for hydration and food.[29] Prioritization may be assisted by providing mothers and caregivers, for example, with a card, note, or lanyard to present to staff.[29] Ensuring women have easy access to toilet facilities will reduce the possibility they will restrict fluid intake and become dehydrated and risk reducing milk production. Providing a separate, supported space in emergency shelters for families with infants and young children can help in providing targeted assistance and safety.[29]

Supporting Mothers, Caregivers, and Children via MBAs

MBAs, also called "Baby Friendly Spaces" and "Baby Tents," have supported the well-being of pregnant women and new mothers and assisted them in caring for their infants and young children during and after emergencies since the Balkan crisis of the late 1990s.[84] MBAs are a safe, comfortable, and welcoming space for mothers and other caregivers of infants and young children to rest, connect with one another, access health care and referral to services, and receive psychological support, help in caring for their children (including feeding), and other supports that can help them and their families.[85] MBAs can be set up within community buildings such as schools or religious or health institutions or in temporary buildings, tents, or caravans and have been deployed in a large number of countries and different emergency types, including earthquakes, hurricanes/cyclones, floods, and war and in refugee camps. Ideally, MBA staff should have expertise in infant and young child feeding and provision of psychological support.

Research conducted by Action Contre la Faim in refugee camps in Cameroon saw women who attended MBAs experiencing less suffering and difficulties with breastfeeding and improved well-being, social support, and interaction with their infants.[34] Support for relactation and wet-nursing can be provided via MBAs. MBAs can be used for controlled distribution of CMF, including instruction in preparation and cleaning of feeding materials.[35] However, care needs to be taken to ensure that this support does not undermine breastfeeding. This may mean that CMF-focused support is provided at separate times from breastfeeding support.[23] MBAs may provide support for only a few days, as occurred in a New Zealand hospital ward after the 2011 Christchurch earthquake,[86] or for many months to a year or more. In an emergency that lasts long-term and with particular food insecurities, MBAs can assist in giving attention to the nutritional status of breastfeeding mothers and to young children, and importantly, ensuring adequate attention to micronutrients.[87] Some mothers may not have the mobility to access an MBA, so it may be important to have skilled breastfeeding supporters available who can travel to mothers who require help. Remote breastfeeding support during a disaster can prove valuable.[53]

Emergency Preparedness Training Curriculum Regarding Breastfeeding

It is essential that emergency relief personnel working with pregnant women, new mothers, and other caregivers of infants and young children be trained to understand the vital role of breastfeeding in emergencies. They should learn the basics of lactation physiology and the WHO recommendations for infant and young child feeding. Aid workers should know the preferred order of feeding options for nonbreastfed infants. They must know that donations of CMF and other breast milk substitutes should not be solicited or accepted and about appropriate and discreet storage and distribution of CMF. Aid workers should be trained to recognize which infants have appropriate needs for CMF, and which mothers should be referred for skilled breastfeeding support (if they do not have these skills themselves). They should be educated about cup feeding and avoidance of feeding bottles and teats. They should know about proper preparation of CMF.

Training of emergency relief personnel working directly with mothers should include how to handle frequently encountered breastfeeding issues, such as mothers reporting stress affecting their milk. Gribble and Palmquist have suggested that emergency relief workers be taught appropriate counseling skills so that they know how to respond to maternal requests for CMF.[41] They suggest aid workers be encouraged to understand the ethical framework underpinning CMF provision requirements in the OG-IFE so that they are better able to respond appropriately to maternal requests.[41] Personnel should be trained to counsel women based on evidence, free from bias from their own personal experiences with CMF.[41] Those working in an IYCF-E role may benefit from debriefing of their own infant feeding experiences and on reflective practice.[41] They should be trained to never advise mothers to stop breastfeeding without a compelling evidence-based medical reason, and that mild maternal illnesses are not a reason to stop breastfeeding.

Emergency relief personnel need to be aware of local cultural beliefs around breastfeeding and be prepared to counsel mothers with accurate information.[28] Finally, emergency relief workers should receive training on the International Code of Marketing of Breast Milk Substitutes (the Code), why CMF donations should not be accepted in an emergency, and how untargeted distribution of CMF undermines breastfeeding and infant and maternal health.

The Role of Medical Doctors in Protection, Promotion, and Support of Breastfeeding During Emergencies

During routine care, doctors should promote breastfeeding to all women as the standard of infant nutrition and provide

the support needed for women to breastfeed in line with international recommendations, and to help them reach their breastfeeding goals.[88] Doctors should emphasize breastfeeding as part of emergency preparedness in locations where emergencies are seasonal, and as part of their usual anticipatory guidance, doctors should advise mothers to continue breastfeeding until after the risk period ends.

Doctors should also work to implement and support the BFHI. High precrisis implementation of the BFHI in Ukraine greatly helped the resiliency and response of mothers and providers during that armed conflict.[53] Conversely, poor hospital practices, such as unnecessary separation of mothers and infants, can undermine the establishment of breastfeeding when it is most needed.

Medical doctors should also encourage direct breastfeeding and discourage the practice of exclusively using breast pumps for feeding when it is not medically necessary. This is especially important for those using electric pumps, given the rising occurrence and duration of power outages in some locations.[89] Doctors should encourage women who are dependent on breast pumps to seek professional help to transition to direct breastfeeding and encourage all women to learn how to hand express even when no emergency exists. Doctors should particularly advise all mothers who exclusively use breast pumps to learn hand expression for times when access to electricity or sanitation is not possible.

Encouragement and support of breastfeeding include enhancing women's confidence in their ability to breastfeed as this has been correlated with breastfeeding success. Conversely, lack of self-efficacy makes it less likely for women to breastfeed during an emergency.[70] This underlines the importance of doctors having not just clinical knowledge but also breastfeeding counseling skills.

Preexisting cultural beliefs may limit uptake of breastfeeding even before the emergency.[28] It may help for doctors to work with other community leaders to understand the underlying issues, and work collaboratively to take into account beliefs and barriers that limit breastfeeding.[33]

During emergencies, doctors should ensure that women who give birth are supported with standards of care that support breastfeeding. Specifically, women and newborns should experience skin-to-skin care in the first hour of life, early initiation of breastfeeding, and the other maternity practices that comprise the WHO/UNICEF Ten Steps to Successful Breastfeeding.[90] During emergencies, doctors who work with women and children can make their offices available as havens for breastfeeding support, if they are able to provide it.[29]

Furthermore, medical doctors, especially those who care for children, should be involved in emergency preparedness plans as governmental and philanthropic organizations may not be aware of the importance of breastfeeding to these plans.

Educating the Public

During an emergency, members of the public, often far from the event, want to help. Members of the public should be encouraged to give monetary donations rather than goods to enable resources to be provided when, where, and in the form required and to avoid the "second disaster" caused by an influx of donations[91] and the particular harms caused by infant feeding-related donations. Breastfeeding mothers living far from the disaster can donate their milk via local milk banks but should not seek to send their milk to the emergency area. The public should be specifically discouraged from donating CMF and from sending CMF to an emergency area.[23]

Other Considerations

It is important to specify that *breastfeeding* is important in emergency situations, not merely *human milk*, and the two terms should not be used interchangeably in policies or elsewhere. While human milk is superior to animal milk or CMF, feeding human milk without direct breastfeeding requires expressing milk and feeding using cups or other equipment, all of which are challenging during an emergency and present hygiene risks, and additionally may not provide the same immune protection to the child.[92]

Lack of emergency preparedness for infant and young child feeding appears to be a global problem.[93–95] Mapping of many plans to deal with humanitarian emergencies has shown inadequate attention to infant and young child feeding issues.[96] Emergency preparedness plans should be audited periodically.

Disaster-Specific Information

Blizzards

Blizzards may leave people trapped in their homes (or other locations) for days, often without electricity. This situation will most affect mothers who exclusively feed pumped milk, and all mothers who have caches of frozen stored milk. If exclusively pumping mothers do not have a manual pump available and/or power to heat water for washing, they should hand express their milk and/or attempt to directly breastfeed their infants. Trained breastfeeding help may only be available remotely and only if there is electricity to power mobile devices or the internet. It is often unknown how long a power outage will last when it begins. One must weigh opening the freezer door against using contents within the freezer. Using stores of frozen milk before using freshly expressed milk may make sense, particularly if there is concern that frozen milk may thaw and spoil. If outdoor temperatures are consistently well below freezing, one can consider moving frozen milk stores outdoors, stored in a container that would be safe from tampering by animals.

All families experiencing power outages will face challenges preparing food for themselves and should follow local guidelines.

Fires

Women and children exposed to wildfires may be exposed to particulate matter on their hair and clothing, and may have inhaled toxins from burning buildings, including polyaromatic hydrocarbons (PAHs). Research from the Australian bushfires of 2019–2020 suggests that the amounts of such PAHs in breast milk were low and no samples contained lead, chromium, nickel, or aluminum.[97] Women should be reassured that there is no concern regarding breast milk and

exposure to bushfire smoke. Women may also be prone to dehydration and missed feeds due to heat and rushed evacuation, leading to compromise of milk production. Rehydration and increased feeding frequency will be necessary. In heavy smoke, infants may be fussy at the breast and come on and off the breast to breathe (similar as to if they have a blocked nose with a cold).[29]

Earthquakes

Earthquakes occur without warning and may result in mother–infant separation or circumstances in which either the mother or infant is either injured or dead. Typically, multiple aftershocks follow the initial earthquake, which may cause further damage and collapse of buildings, causing uncertainty and anxiety. In China, concern about future collapse of hospital buildings led to a marked increase in cesarean deliveries to eliminate uncertainties about birth timing.[98] Families may be in temporary housing for extended periods of time and may be without reliable power, clean water, or food. Skin-to-skin contact for infants may be especially important to keep infants warm and calm if availability of safe warm shelters is limited. Concern regarding aftershocks may result in mothers being unwilling to put their infants down, which will support frequent and continued breastfeeding.

Floods

Floods, including those accompanying hurricanes and typhoons, are often complicated by the contamination of floodwaters with raw sewage and chemical toxins, which then also contaminate drinking water and any surfaces the water touches. Breastfeeding is particularly important because of the protective impact of breast milk against diarrheal disease and because the availability of safe clean water to wash infant feeding supplies and reconstitute CMF may be compromised. Mothers who exclusively pump their milk are at high risk and should be aided in transitioning to direct breastfeeding as soon as possible.

Armed conflicts

A systematic review has shown that despite its importance to child survival, breastfeeding is reduced in areas of conflict.[99] Armed conflict situations tend to last longer than those of natural disasters. Therefore, the nutritional needs of children may be a long-term concern. For example, infants older than 6 months are unlikely to have severe nutritional deficiencies within one to two weeks if they are not fed appropriate complementary foods. Over the course of months, however, it is important to ensure that the nutritional status of such infants is stable, including adequate macro- and micronutrients. Supporting infant and young child feeding during armed conflict can be particularly challenging as personnel and supply access to affected populations may be difficult or impossible.

Armed conflict often has constantly changing areas that are impacted. The impact to structures such as roads and water lines may be similar to that of natural disasters, but there is the additional challenge of providing services under fire. Emergency plans need to include protections of mothers and infants from aerial attack (bomb shelters) and supply distribution to civilians in battle conditions. As with earthquakes, there may be situations in which either mother or child is either injured or dead and the same supportive provisions apply.

The possibility of sex-based violence adds to all the other factors that make uptake of exclusive breastfeeding challenging in armed conflict.[28] In addition, attention to both cross border and internally displaced refugees is needed.[27]

Nuclear power plant accidents

The IFE Core Group has issued guidance on management for breastfeeding mothers and children in the first three days after a nuclear power plant accident, noting specifically that this guidance does not apply to nuclear weapons.[100]

Potassium iodide (KI) is recommended for breastfeeding women and breastfeeding children because nuclear plant accidents cause emission of an iodine isotope (I-131), which can damage the thyroid. KI prevents this isotope from entering the thyroid gland. It should only be taken if authorities recommend it.[100]

In nearly all cases, continuation of breastfeeding is recommended. The rare advice to temporarily stop breastfeeding is if the mother–infant pair was very close to the reactor, *and* cannot shelter in a safe location, *and* KI is not available, *and* the mother either has previously expressed milk available *and* access to safe feeding and cleaning supplies, or a safe supply of CMF and a safe way to prepare it.[100]

Infectious disease outbreaks

Infectious disease outbreaks, including epidemics and pandemics, can pose challenges to infant feeding. The IFE Core Group has published two infographics to guide policy makers and program managers on the management of infant and young child feeding in infectious disease outbreaks.[101] Their recommendations emphasize support of breastfeeding when it is known that breastfeeding is safe with a particular infection, and how to support breastfeeding when the type of infection requires temporary disruption of breastfeeding.

There may be circumstances in which a new pathogen emerges and the safety of breastfeeding is initially in question. In these cases, health authorities will seek expert opinions, which would weigh factors such as the likelihood that the pathogen can be transmitted via milk, and if so, whether it is likely to cause significant disease in infants by that route, and whether the pathogen could be spread to the infant by other routes during breastfeeding. For example, a pathogen may be spread by a respiratory route during feeding, which could occur regardless of the feeding method, and may be preventable by appropriate respiratory precautions. Health decision science can be used to inform interim guidance[102,103] until recommendations from the World Health Organization are available.[104]

Failure to appreciate the value of breastfeeding has had public health consequences during epidemics with new pathogen epidemics. When breastfeeding is assumed to be something dispensable, the default assumption is often it is safer not to breastfeed in situations of unknown safety.[105] Similarly, failure to appreciate the comparative risks of CMF feeding can lead to recommendations in which it is inappropriately recommended over breastfeeding, particularly in low-resource settings in which CMF is not acceptable,

feasible, affordable, sustainable, and safe. Such early guidance around HIV was responsible for the unnecessary deaths of many infants.[106] Early in the COVID-19 pandemic, many health authorities immediately created policies of separation of infants from their mothers combined with CMF feeding over breastfeeding, which again likely resulted in unnecessary infant deaths.[107,108] Breastfeeding specialists can play an important role in informing policy makers regarding the importance of breastfeeding and the risks of CMF feeding to ensure that both are appropriately taken into consideration when developing recommendations.

In the case of a new pathogen, when international guidance from the World Health Organization is not yet available, the IFE Core Group recommends that continuation of breastfeeding be prioritized and that close mother–infant contact be maintained until and unless there is good evidence to inform that ceasing breastfeeding is safer.[104] If women cease breastfeeding because of infectious disease concerns, they should be supported to maintain their milk production so that they can resume breastfeeding when they recover or if this is not possible, they be supported to relactate.

Prolonged heat and other climate change issues

Long-term extreme heat can contribute to drought and food insecurity, and prompt migration of large numbers of people. Hot weather is associated with reduced rates of exclusive breastfeeding that may be a result of less time spent breastfeeding or maternal dehydration.[109,110] The UNICEF Technical Note, *Protecting Children from Heat Stress*, provides guidance on how to help protect pregnant women, new mothers, and infants from extreme heat.[110] In the face of adverse climate change impacts, breastfeeding provides an opportunity for mitigation, adaptation and community resilience.[111]

Other emergency experiences

Other emergencies include those related to refugee camps, volcanic eruptions, landslides, tornados, famines, tsunamis, building collapses, and fires that may destroy a single large building (such as London's Grenfell Tower Fire of 2017). In addition, there is the possibility of unconventional warfare. The IFE Core Group has information on chemical, radiological, and biological attacks.[112] Slowly, developing emergencies, including famines and drought, often have extended periods of food insecurity. Breastfeeding remains vitally important in such emergencies, but attention also must be paid to maternal nutrition. Each type of emergency will have its challenges but the general principles will remain the same.

Summary

Protection, promotion, and support of breastfeeding before any emergency are critically important. It is essential to promote exclusive breastfeeding during routine care, and provide the infrastructure to enable mothers to exclusively breastfeed during ordinary times. During a disaster, breastfeeding provides an important lifeline and breastfeeding support must be part of all emergency preparedness plans, policies, and training impacting families with infants and young children. Education of emergency relief personnel in the importance of breastfeeding and in the basics of breastfeeding management is vital. Given that mothers who are dependent on breast pumps are extremely vulnerable during emergencies, extra efforts should be made to discourage this practice and promote direct breastfeeding during routine care of mothers with newborns. Nonbreastfed infants are a vulnerable group and they and their caregivers require special support. Breast milk options for these infants should be first explored and if breastfeeding is not possible, they should be provided with a comprehensive package of support.

Future Directions

As the climate crisis continues to evolve, there will be more climate emergencies as well as migrations and climate refugees. Technology will affect types of armed conflict and ways in which we can support breastfeeding. Data regarding infant feeding should be part of information gathered in emergency situations so that global learning can occur and lead to improvements from one event to the next.

For an additional resource supporting the recommendations outlined in this position statement, please visit our website at //bfmed.org/position-statements to access a complementary handout.

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For correspondence: abm@bfmed.org

s22

From: s47E(c), s47F
Sent: Tuesday, 8 October 2024 10:47 PM
To: Jonathan Chew
Cc: s47E(c), s47F
Subject: RE: The Trade Mark Letter [SEC=OFFICIAL]

Hi Jonathon
Anthea is keen
I've asked her EA to make the arrangements (most likely 2:30pm)
Kind regards
s47E(c), s47F

From: Jonathan Chew s47F @infantnutritioncouncil.com>
Sent: Tuesday, October 8, 2024 2:19 PM
To: s47E(c), s47F @Health.gov.au>
Cc: s47E(c), s47F @Health.gov.au>
Subject: Re: The Trade Mark Letter [SEC=OFFICIAL]

Hi s47E(c), s47F

The Chair of the INC, Maria Venetoulis, and I will be in Canberra for the day on Thursday 17 October.

Would there be any chance that the new AS, Anthea Raven, would be available for a meeting that day, between 12.30 and 3pm?

(I'm not certain Anthea is based in Canberra, but thought I'd ask anyway).

Cheers
Jonathan

From: Jonathan Chew s47F @infantnutritioncouncil.com>
Date: Thursday, 26 September 2024 at 10:32 AM
To: s47E(c), s47F @Health.gov.au>
Cc: s47E(c), s47F @Health.gov.au>
Subject: Re: The Trade Mark Letter [SEC=OFFICIAL]

Hi s47E(c), s47F

Thanks for your email – so many changes! I will try to give you a call today just to touch base on where we are. Perhaps after Anthea settles in, we can arrange another call in due course.

Cheers
Jonathan

From: s47E(c), s47F @Health.gov.au>
Date: Thursday, 26 September 2024 at 7:12 AM
To: Jonathan Chew s47F @infantnutritioncouncil.com>
Cc: s47E(c), s47F @Health.gov.au>
Subject: RE: The Trade Mark Letter [SEC=OFFICIAL]

Hi Jonathon
Regarding a meeting with Tracey – I'm sorry to advise that her last day with the branch was yesterday. She is now on leave and will return to a new role. s22 Anthea Raven starts on Monday.
In good news, however, Tracey approved the Trade Mark letter last yesterday evening. Her EA will apply eSig etc this morning so we will be able to get that to you today.
Again, I'm sorry that you weren't able to connect with Tracey
Kind regards
s47E(c) s47F

From: Jonathan Chew s47F @infantnutritioncouncil.com>
Sent: Wednesday, September 25, 2024 5:30 PM
To: s47E(c), s47F @Health.gov.au>
Subject: The Trade Mark Letter

Hi s47E(c) s47F

Just following up a couple of matters:

1. Couldn't speak with Tracey today, and I'm out all tomorrow, but maybe there's a window on Friday? I have a call between 10.30 – 11.30, but otherwise have flexibility until 4pm.

2. How are you going with the Trade Mark letter? We are submitting on Friday so if it's possible to have it by OOB Friday, that would be very much appreciated.

Many thanks

Jonathan

s22

From: Jonathan Chew s47F @infantnutritioncouncil.com>
Sent: Wednesday, 9 October 2024 8:57 AM
To: s47E(c), s47F
Cc: s47E(c), s47F
Subject: Re: Meet with Anthea Raven - Preventive Health and Food Policy Branch [SEC=OFFICIAL]

Hi s47E(c), s47F

Yes, thank you, that works well.

Maria's email is s47F

We look forward to meeting Anthea next week.

Cheers
Jonathan

Sent from my iPhone

On 9 Oct 2024, at 08:47, ROWLAND, Karen <Karen.Rowland@health.gov.au> wrote:

Good morning Jonathon

s47E(c), s47F forwarded your email regarding a meeting with Anthea Raven next Thursday 17 October, for you and Maria Venetoulis.

Anthea would be pleased to meet with you both next Thursday at 2.30pm. Would this time be suitable for you both. If so, I can send through an invitation, providing our address and contact details for when you arrive.

Can I confirm Maria's email would be: s47F @infantnutritioncouncil.com

Looking forward to hearing from you.

Kind regards s47E(c), s47F

s47E(c), s47F

Executive Assistant to Anthea Raven – Assistant Secretary Preventive Health & Food Policy Branch

Population Health Division | Primary and Community Care Group
Australian Government, Department of Health and Aged Care

T: 02 s47E(c), s47F | E: s47E(c), s47F @health.gov.au
Location: Yaradhang 5.S.214
GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

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s22

From: Jonathan Chew s47F @infantnutritioncouncil.com>
Sent: Monday, 23 September 2024 11:08 AM
To: s47E(c), s47F
Subject: Infant Nutrition Council: ACCC/MAIF Agreement

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Hi s47E(c), s47F

I left a phone message as well. I'd be grateful if we could have a chat about the ACCC draft determination that was released on Friday with respect to the MAIF Agreement? We have our committee meeting at 3pm, and I'm on other calls after that. Would it be possible to speak between 12.30pm and 3pm?

My best number is my mobile s47F.

Cheers
Jonathan

Jonathan Chew
Chief Executive Officer

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